



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Wexford General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Newtown Road, Carricklawn, Wexford
Type of inspection:	Announced
Date of inspection:	26 May 2022
Medical Radiological Installation Service ID:	OSV-0007382
Fieldwork ID:	MON-0035042

About the medical radiological installation:

Wexford General Hospital (WGH) is part of the Ireland East Hospital Group. WGH is governed by a board of management which is chaired by the general manager. WGH is a 280-bedded hospital providing a diagnostic imaging service for both the adult and paediatric population in the Wexford catchment area and a specialised radiology service for the South Eastern population. Hospital services include a 24/7 accident and emergency department, acute medical assessment unit, general medicine, general surgery, care of the elderly including day hospital, day procedures, out-patient department and clinics, paediatrics, oncology, obstetrics and gynaecology, pharmacy, medical science laboratory, speech and language therapy, occupational therapy, physiotherapy, dietetics, cardiology, chiropody and department of nursing providing specialist nursing services.

The radiology department in WGH provides general radiography, emergency X-rays, mobile radiography, fluoroscopy, ultrasound and computed tomography (CT) with a hospital wide national integrated medical imaging system (NIMIS), radiology information system (RIS), picture archiving and communication system (PACS). The department operates Monday to Thursday 08:30 to 17:00 and Friday 09:00 to 17:00 and provides a 24/7 on-call service providing out-of-hours radiography and CT service for the emergency department and in-patients. The radiology department in WGH comprises of four general X-ray rooms including a digital chest room, a digital X-ray room which was upgraded in 2020 and two additional X-ray rooms which have also been retrofitted as digital radiography units. In addition, the department has a newly installed fluoroscopy unit, a CT scanner and three mobile units, one of which is a digital unit.

How we inspect

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

As part of our inspection, where possible, we:

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

About the inspection report

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

1. Governance and management arrangements for medical exposures:

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

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

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

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

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Thursday 26 May 2022	09:30hrs to 16:30hrs	Kirsten O'Brien	Lead
Thursday 26 May 2022	09:30hrs to 16:30hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

An inspection of Wexford General Hospital was carried out on the 26 May 2022 by inspectors to assess compliance against the regulations. As part of this inspection, inspectors visited the radiology department, including the general radiography (X-ray), fluoroscopy and computed tomography (CT) areas.

The general manager (GM) of the hospital was the named designated manager and the person responsible for the radiation protection of service users at Wexford General Hospital. A radiation safety committee (RSC), which reported into the quality and patient safety executive committee, was in place which held meetings twice a year. The RSC was found to be the main overarching measure for the provision of formal oversight regarding the radiation protection of service users at the hospital. The GM was not a member of the RSC but was a member of the quality and patient safety executive committee. However, the operations manager clinical services was a member of both the RSC and the quality and patient safety executive committee. From speaking with management on the day of inspection, inspectors found that the operations manager clinical services was the individual responsible for providing feedback and oversight to the GM primarily through line management arrangements but also through membership of the RSC and the quality and patient safety executive committee. For example, the radiography services manager (RSM) reported up to the clinical directorate services manager, who in turn reported up to the GM.

On the day of inspection, governance and management arrangements in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital were reviewed by inspectors. While inspectors were satisfied that appropriate governance and management structures were in place at Wexford General Hospital, overarching governance and management arrangements, through the Health Service Executive's (HSE) National Radiation Protection Office (NRPO), were not clearly communicated to inspectors. Additionally, documentation should be reviewed and updated to ensure that local governance arrangements are accurate and consistent with day-to-day practice at the hospital. An updated organogram of local governance arrangements was submitted to HIQA as requested following the inspection.

A service level agreement was in place to ensure appropriate medical physics expert (MPE) involvement, however, inspectors were not fully assured that an MPE contributed adequately to the analysis and dosimetry of events involving, or potentially involving, accidental or unintended exposures to ionising radiation. Furthermore, from a review of documentation submitted to HIQA following the inspection, an area for improvement was noted regarding the responsibility of the HSE, as the undertaking, to ensure the contribution of an MPE in the preparation of technical specifications for all medical radiological equipment and installation design at the hospital.

Notwithstanding the areas for improvement identified over the course of the inspection, inspectors were satisfied that all medical radiological procedures took place under the clinical responsibility of a practitioner, as defined in the regulations. There was evidence that referrers and practitioners were involved in the justification of individual medical radiological procedures. Furthermore, radiographers, radiologists and an MPE were found to be involved in the optimisation of medical exposures at the hospital.

Regulation 4: Referrers

On the day of inspection, inspectors reviewed a sample of referrals and spoke with staff and were satisfied that referrals for medical radiological exposures were only accepted at the hospital from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

From speaking with staff and management at Wexford General Hospital, and reviewing a sample of records and other documentation, inspectors were assured that only individuals entitled to act as a practitioner took clinical responsibility for medical exposures at the hospital.

Judgment: Compliant

Regulation 6: Undertaking

The allocation of responsibility within Wexford General Hospital for radiation protection was reviewed over the course of the inspection. Inspectors also spoke with staff and management and reviewed policies, records and a diagram of local governance structures (organogram) for medical exposure to ionising radiation at the hospital. On the day of inspection, Wexford General Hospital was found to have only allocated responsibility for radiation protection to appropriate individuals as required by the regulations. However, the overarching governance and management arrangements of the HSE, as the undertaking, through the NRPO, were not clearly communicated to inspectors on the day.

The GM was the named designated manager by the HSE with responsibility for the radiation protection of service users at Wexford General Hospital. A RSC which met twice a year was identified as the main formal forum for governance and oversight for the radiation protection of service users attending the hospital. Members of the

RSC included personnel both internal and external to the radiology department. While the core membership of the RSC was found to be limited, management provided an assurance that membership was commensurate with the scale of radiological services provided at the hospital and other relevant stakeholders, such as referrers, were included as required.

As the GM was not a member of the RSC, inspectors were informed that other mechanisms were in place which provided oversight of any issues arising relating to the radiation protection of services users. The operations manager clinical services was the individual responsible for providing feedback to the GM through line management arrangements. For example, the radiography services manager (RSM) reported up to the operations manager clinical services, who in turn reported up to the GM. An additional oversight mechanism included communication from the RSC into the quality and patient safety executive committee by the operations manager clinical services and the clinical risk manager who were members of both committees.

Inspectors were satisfied that given the size and scale of the hospital, appropriate feedback mechanisms were in place through key individuals and line management structures in order for the GM to ensure the radiation protection of service users at the hospital. Although oversight mechanisms for governance and reporting regarding medical exposure to ionising radiation at the hospital were explained to inspectors, these were not accurately described in policies and documentation. An updated diagram of the governance structure for radiation protection of service users, encompassing the role of the undertaking and the designated manager, was submitted to HIQA following the inspection as requested.

Overall, while inspectors were satisfied that governance and management structures were in place at the Wexford General Hospital, documentation showing a clear allocation of responsibility was an area of improvement to ensure clarity of local governance and oversight arrangements at the hospital including the overarching management structure of the HSE as the undertaking for the hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

All medical exposures for ionising radiation at Wexford General Hospital were found to be carried out under the clinical responsibility of an individual entitled to act as a practitioner. From speaking with staff and reviewing a sample of referrals and other documentation, inspectors were assured that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological procedures.

The practical aspects of medical exposures were only carried out by persons entitled to act as a practitioner. Inspectors also found evidence that practitioners and MPEs

were involved in the optimisation process for medical exposures.

Additionally, Wexford General Hospital had retained the presence of radiographers in areas where medical exposures were conducted in conjunction with other non radiology specialties such as in theatre. In the absence of new training requirements being implemented, as per Regulation 22, this is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from communication with staff and management and a review of relevant policies, records and a service level agreement, that Wexford General Hospital had adequate processes in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors spoke with staff and management and reviewed documentation and other records to establish the involvement and contribution of an MPE to areas such as, diagnostic reference levels (DRLs), quality assurance (QA) programmes, acceptance testing and the analysis of events involving or potentially involving an accidental or unintended exposure to ionising radiation. Inspectors found that an MPE was adequately involved in the majority of areas, however, MPE involvement and contribution to the radiation protection of service users at Wexford General Hospital was not fully in line with all requirements as outlined in Regulation 20.

Inspectors found that MPE contribution and involvement in carrying out dosimetry following all accidental or unintended exposure was an area that must be strengthened at the hospital. Records and documentation requested by inspectors specifically regarding the dosimetric calculations by an MPE for two accidental or unintended exposures was not provided. Additionally evidence requested for submission to inspectors following the inspection to demonstrate that an MPE had contributed to the analysis of one accidental or unintended exposure that occurred in CT was also not provided.

Similarly, while an example of MPE contribution to the preparation of technical specification for medical radiological equipment and design was provided on the day of inspection, documentation reviewed following the inspection did not fully assure inspectors that the HSE, as the undertaking, had measures in place to ensure the

appropriate contribution of an MPE in the preparation of technical specifications for all medical radiological equipment at the Wexford General Hospital.

Judgment: Substantially Compliant

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

Staff who spoke with inspectors reported that they had good access to medical physics expertise as needed. Documentation reviewed also provided evidence that formal arrangements were in place at the hospital to ensure that access to an MPE was available, commensurate with the radiological risk, at the hospital. However, as per Regulation 20, MPE contribution to the analysis and dosimetry of accidental or unintended exposures to medical exposure was identified as an area of improvement at Wexford General Hospital.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at Wexford General Hospital. Written protocols were available for standard medical radiological procedures. Leaflets containing information about the benefits and risks associated with medical exposure to ionising radiation were sent with appointment letters to patients attending the hospital for a medical radiological procedure.

Staff informed inspectors that radiographers or radiologists justified all medical exposures in advance of each procedure. Inspectors reviewed a sample of referrals for medical exposures on the day of inspection. 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. Justification in advance was also found to have been recorded by a practitioner. Consideration was also given to the justification of the exposure of carers and comforters to ionising radiation and measures had been put in place to ensure that dose constraints were used to ensure the radiation protection of individuals acting as carers and comforters at the hospital.

Documentation and other records of medical exposures were reviewed by inspectors who also spoke with staff over the course of the inspection. The hospital had a number of measures and initiatives in place to ensure that all doses due to medical radiological procedures were kept as low as reasonably achievable (ALARA) consistent with obtaining the required information.

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 staff, including referrers and practitioners could clearly describe this process to inspectors.

On the day of inspection arrangements were found to be in place regarding the recording of events involving, or potentially involving, accidental and unintended exposures to ionising radiation. Inspectors were also satisfied that the hospital had arrangements in place to ensure that HIQA was notified of the occurrence of significant events, as required by the regulations. However, inspectors spoke with staff and management, reviewed documentation and other records, and identified that the analysis and assessment of risk reduction mechanisms in relation to events involving an accidental or unintended exposure to ionising radiation to prevent the occurrence or reoccurrence of such events, as an area for improvement at the hospital. The undertaking and management at the hospital must ensure that measures are put in place to ensure that all reasonable measures are taken to minimise the probability and magnitude of actual incidents.

While areas for improvement were noted during the inspection, inspectors were satisfied that Wexford General Hospital had systems in place to help ensure safe delivery of medical exposure to ionising radiation.

Regulation 8: Justification of medical exposures

Information relating to the benefits and risks associated with medical exposures were placed in the main waiting rooms. Bespoke information leaflets were also sent out with appointment letters to patients for all medical radiological modalities.

All referrals reviewed were in writing and stated the reason for requesting the particular procedure. Staff informed inspectors that medical exposures were justified by a practitioner in advance of each medical radiological procedure. A sample of referrals for medical exposures to ionising radiation were reviewed on the day of inspection and justification in advance was found to have been recorded by a practitioner. While evidence of compliance was found on the day of inspection regarding recording out-of-hours justification of CT examinations in advance, inspectors identified this as an area for review with the possibility of improving the processes in place for recording justification in advance for these procedures.

From speaking with staff in the clinical areas, inspectors were also assured that consideration was given to the justification of the exposure of carers and comforters to ionising radiation. Similarly, staff described several examples of good practice regarding the justification of medical exposures, for example, the application of evidence based referral guidelines to ensure that only appropriate examinations were carried out at the hospital.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed a sample of documentation and other records of medical exposures, and spoke with staff over the course of the inspection and found that the hospital had a number of measures in place to ensure that all doses due to medical radiological procedures were kept as low as reasonably achievable consistent with obtaining the required information. An example of optimisation was an annual multidisciplinary dose optimisation report which was noted as an area of good practice. This report included an evaluation of the diagnostic quality of images obtained in CT, general radiography and fluoroscopic procedures. Optimisation measures for the practical aspects of CT procedures and quality assurance for medical radiological equipment at the hospital were also included in the report.

The hospital had also established guidance for carers and comforters which included information about the benefits and risks of exposure to ionising radiation. Inspectors spoke with staff who explained how this guidance was provided to carers and comforters prior to the medical exposure taking place and how they ensured adherence to the ALARA principle to ensure optimisation of radiation dose to individuals acting as carers and comforters at the hospital.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Wexford General Hospital had established DRLs for radiodiagnostic procedures and for interventional radiology procedures, where appropriate. However, while most DRLs were regularly reviewed, paediatric DRLs for general radiography had not been reviewed annually in line with best practice and the hospital's own DRL policy. Consequently, the hospital should ensure that all DRLs are reviewed regularly having regard for national DRLs where available.

Judgment: Substantially Compliant

Regulation 12: Dose constraints for medical exposures

A record of the radiation dose arising from the medical exposure was recorded and retained following the procedure by the hospital. Staff 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 the

hospital.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical radiological procedures. These were also available to staff electronically on a shared drive and in hard copy. Wexford General Hospital had adopted referral guidelines which were available to referrers on the hospital's intranet. Inspectors also reviewed a sample of clinical audits carried out at the hospital.

On the day of inspection, based on a sample of records reviewed, information relating to patient exposure did not form part of the report of medical radiological procedures. Inspectors were informed that although measures had been put in place by the HSE to come into compliance with Regulation 13(2), these measures were no longer being implemented by practitioners in this hospital. The HSE, as the undertaking for Wexford General Hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure compliance measures are implemented in Wexford General Hospital relating to Regulation 13.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection. Inspectors were satisfied that appropriate quality assurance programmes, which included an assessment of dose, were in place to ensure that medical radiological equipment at the hospital was kept under strict surveillance. Inspectors also reviewed records of performance testing and were satisfied that testing was carried out on a regular basis and a mechanism to report any equipment faults or issues arising from testing was in place. From records reviewed, inspectors were satisfied that acceptance testing was also carried out before first clinical use.

On the day of inspection, a large proportion of medical radiological equipment at Wexford General Hospital hospital was identified as being past its nominal replacement date. Inspectors did note that while an equipment replacement programme for medical radiological equipment was in place, the HSE, as the undertaking, should ensure that opportunities for the further optimisation of medical exposures, in line with the technological advancements, in medical radiological equipment are availed of where appropriate.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Multiple notices were observed in waiting and changing rooms to raise awareness of the special protection required during pregnancy in advance of medical exposures. Referrers and practitioners inquired, and recorded in writing, the pregnancy status of service users, where relevant. Where pregnancy could not be ruled out, practitioners and referrers spoken with on the day of inspection, communicated to inspectors how special attention was given to the justification, and the manner in which this was recorded.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

During the inspection, arrangements to record and analyse incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation were reviewed. Inspectors also assessed measures put in place to minimise the probability of reoccurrence of accidental and unintended exposures to ionising radiation at the hospital by speaking with staff and management and reviewing documentation and other available records. Inspectors were satisfied that the hospital had mechanisms in place to ensure that HIQA was notified of the occurrence of significant events, as required by the regulations. However, the results of the investigation into a significant event reported to HIQA and the corrective measures to avoid such events lacked the specific details required by HIQA as outlined in guidance documents. However, further information about this incident was subsequently provided when requested.

Arrangements were found to be in place regarding the recording of events involving, or potentially involving, actual accidental and unintended exposures to ionising radiation. Inspectors found that Wexford General Hospital had identified an issue regarding duplicate referrals to multiple sites including Wexford General Hospital, and other hospitals in the region. This had resulted in service users receiving an additional unintended or accidental exposure to ionising radiation. A solution was communicated to inspectors, however this was found to be a long term solution which would not be available for implementation for a number of years and subsequently would not minimise the probability of a similar incident reoccurring in the short to medium term. Consequently, inspectors were not assured that all potential solutions had been fully explored to ensure that reasonable measures had been taken in a timely manner to minimise the probability and magnitude of events involving accidental and unintended exposures to ionising radiation as a result of duplicate referrals for medical exposures in the region.

Records of other accidental and unintended exposures to ionising radiation which had occurred at the hospital were reviewed and inspectors also spoke with management about the process in place for analysing events involving, or potentially involving, accidental and unintended exposures to ionising radiation. Inspectors found that an appropriate system for the analysis of such events was not in place. For example, national incident management system (NIMS) forms and data about each incident in a spreadsheet were reviewed. Although, the spreadsheet included charts which identified high level trending of the types of incidents that had occurred, no evidence was provided to show that a sufficient analysis of each individual incident had taken place, for example to identify causation, corrective actions or lessons learnt. Additional documentation relating to two incidents was requested to provide evidence of the specific investigation and dosimetry calculations carried about for these two incidents. Where some information was subsequently submitted to HIQA, this documentation did not demonstrate compliance with the requirements of Regulation 17(1)(c).

The analysis of events involving, or potentially involving, accidental or unintended medical exposures was identified as an area for improvement at the hospital. Ensuring that an appropriate multidisciplinary team is involved in analysing events, including risk assessment and reduction mechanisms, offers an opportunity for learning and would assist both management at the hospital and the undertaking in identifying and exploring all appropriate measures to minimise the probability and magnitude of incidents involving accidental or unintended medical exposures occurring at the hospital.

Notwithstanding the areas for improvement identified under this regulation, inspectors found that there was a positive culture of reporting amongst staff who communicated the process for recording and reporting incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation to management.

Judgment: Not Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Substantially 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	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant

Compliance Plan for Wexford General Hospital OSV-0007382

Inspection ID: MON-0035042

Date of inspection: 26/05/2022

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: Documentation to include HSE as the undertaking and Hospital Manager as Designated Manager has been updated/revised and circulated.</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: The RSM and Clinical Risk Manager will develop a process map which will incorporate the requirement to include the MPE in Root Cause Analysis Reviews for relevant radiology incidents. This will be devised and implemented by 31.07.2022.</p> <p>In relation to Procurement of Radiological Equipment it has been agreed that the MPE as part of a MDT will consider all approvals for purchase of equipment in advance of orders being placed. Please note equipment is approved for replacement centrally and from a national framework.</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: As per Regulation 20 above, the RSM and Clinical Risk Manager will develop a process map which will incorporate the requirement to include the MPE in Root Cause Analysis Reviews for relevant radiology incidents. This will be devised and implemented by 31.07.2022.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Preliminary DRL Audit has been undertaken, sample size in each weight band is low therefore preliminary DRLs have been established. More comprehensive data will be available over time. National DRLs are also available for reference.</p> <p>Audit complete.</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Non compliance with SI 256 has been escalated to the CEO and Director of QPS in IEHG for escalation to Acute Hospitals Division, HSE.</p> <p>A local Risk Assessment form is in the process of completion and the non-compliance with regulation will be considered for the hospital's Risk Register.</p>	
Regulation 17: Accidental and unintended exposures and significant events	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:</p>	

1. To avoid accidental and unintended exposures our local CT consent form and Patient Holding Form will be revised to include questions regarding previous imaging. Also, our Radiation Safety Procedure document (Section 8.4 Checklist for prevention of accidental exposure) highlights steps to take in order to avoid such incidents. Completed as of 18/07/22.
2. Radiation Safety Plan (Section 8.3 Incidental and Accidental Reporting) and Radiation Safety Procedures (Section 8.9.2 Equipment Safety and Incident Reporting) gives clear instructions as to steps to follow in the event of an incident. All documents readily available to all Radiology staff both electronically and in hardcopy format. Completed as of 18/07/22.
3. Incidental and Accidental Reports (Section 5) are on the standing agenda at all Radiation Safety Committee meetings attended by multidisciplinary team members. Going forward any incidental and accidental reports will also be on the agenda for all Radiology monthly team meetings for discussion. Standing agenda for team meeting in Radiology will be revised to include Incidental and Accidental reports under the subheading of Radiation Safety. To be completed by 31/07/22.
4. A local WGH Radiology Report of Investigation and findings of patient radiation incident will be implemented (see attached proposed template). This report includes details of recommendations and actions to be taken to prevent recurrence along with clear lines of accountability. All reports will be discussed at Radiation Safety Committee meetings and signed by appropriate individuals. Outcomes will be discussed at Radiology team meetings. To be implemented in line with local approval channels. Estimated date to be complied with 31/08/22.

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	27/05/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional	Not Compliant	Orange	13/06/2022

	radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
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	31/12/2022
Regulation 17(1)(a)	An undertaking shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,	Not Compliant	Orange	31/08/2022
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the	Not Compliant	Orange	31/08/2022

	radiological risk posed by the practice,			
Regulation 20(2)(c)	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: (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	Substantially Compliant	Yellow	31/07/2022

	<p>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	31/07/2022
Regulation 21(2)(b)	<p>In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high</p>	Substantially Compliant	Yellow	31/07/2022

	doses as referred to in Regulation 15(c), a medical physics expert shall be involved, and			
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