

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:	18 February 2025
Medical Radiological Installation Service ID:	OSV-0007382
Fieldwork ID:	MON-0044592

About the medical radiological installation (the following information was provided by the undertaking):

Wexford General Hospital (WGH) is part of the Ireland East Hospital Group (IEHG) 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-hour Accident & 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 & Gynaecology, Pharmacy, Medical Science Laboratory, Speech & 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 RIS/PACS (NIMIS) system. The department operates Monday to Friday 9am-5pm and provides a 24/7 on-call radiographer service providing out-of-hours radiography for the 24 hour Emergency Department, In-Patients and CT. The Radiology Department in WGH comprises of 4 general x-ray rooms, as of 2023 all general room are digital units including one digital erect chest room. In addition the department has three digital mobile units, a fluoroscopy unit installed in 2021 and a CT scanner.

The Radiology department staff complement includes Consultant Radiologists, Radiography Services Manager, Clinical Specialist Radiographers, Senior Radiographers, Staff Grade Radiographers, Nurse, Radiography Assistant and Clerical staff.

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, as amended. 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 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.

1. Governance and management arrangements for medical exposures:

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 18 February 2025	09:00hrs to 14:35hrs	Margaret Keaveney	Lead
Tuesday 18 February 2025	09:00hrs to 14:35hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

During this inspection of the radiological service at Wexford General Hospital, inspectors visited the CT unit, the fluoroscopy room and the general X-ray rooms, and spoke with staff, to monitor the service's ongoing compliance with the regulations. Inspectors also followed up on the compliance plan actions from the previous inspection in May 2022. Overall, inspectors were assured that the undertaking's management team had addressed many of the issues identified during the previous inspection and had made good efforts to achieve compliance with the regulations. However, action was required under Regulations 6, 10 and 13 to improve compliance with these regulations. This is further discussed throughout the report.

The Health Service Executive is the undertaking for Wexford General Hospital, and from discussions with staff, inspectors were informed of the oversight arrangements that the undertaking had in place in the service for radiation protection of service users. Inspectors noted that although the undertaking's management team had made efforts to improve documentation of these arrangements, as discussed under Regulation 6 below, further action was required to ensure a clear allocation of these roles and responsibilities in the service.

The undertaking's management team had established a radiation safety committee (RSC), which met twice yearly. The terms of reference for this committee included details of the membership which inspectors noted was multi-disciplinary. Although a representative from the nurse referrer group did not routinely attend the RSC meetings, inspectors were informed of an informal communication pathway from the RSC to the nurse referrer group. The undertaking should consider strengthening this arrangement as it currently relies on one member of the RSC to meet with the nurse referrer group. The RSC meetings were chaired by a lead radiologist, and were also attended by, among others, the Radiography Services Manager (RSM), a medical physics expert (MPE), the Radiation Protection Officer, and the Operations Manager Clinical Services. The Operations Manager was responsible for updating the General Manager Wexford General Hospital, who was the Designated Manager (DM) in the service, of any pertinent issues that were discussed at the RSC. Inspectors were also informed that the RSM met with the DM at a daily huddle for senior management staff, and through this had further opportunities to inform them of any radiation protection issues in the radiology department.

Inspectors were also informed that the undertaking had established a Radiation Protection Unit, which was attended by the RSM, RPO and MPE teams. The group met every six to eight weeks to provide regular oversight of operational radiation protection matters such as the equipment quality assurance (QA) programme, incidents and clinical audit topics. Matters discussed at this meeting were then brought to the RSC.

Inspectors reviewed a sample of RSC reports generated by the RSM and subsequently presented at the hospital's Quality and Safety Executive Committee (QSEC) meeting twice yearly. Inspectors noted that matters such as concerns about gaps in radiography staffing levels in the department and the potential impact this may have on the safety of the service, the replacement of radiological equipment, clinical audits on the radiology service and the items on the risk register pertaining to the radiology department were included in the report. A review of the QSEC meeting minutes showed the DM and the Operations Manager Clinical Services attended these meetings, and thereby had further opportunities to be updated on the radiation protection of service users at Wexford General Hospital. Inspectors were informed that the DM meets with the hospital's Integrated Healthcare Area manager and that through this arrangement the undertaking representative is subsequently informed of radiation protection measures in the service. The documentation in place, outlining these reporting arrangements from the DM to the undertaking, was identified as an area for improvement within the service, and was discussed with the management team during the inspection.

On the day of the inspection, a sample of service user records for medical exposures were reviewed and demonstrated that appropriate persons, as per the regulations, had been allocated roles and responsibilities relating to radiation protection of service users within the service. However, inspectors identified that, for a sub-set of medical exposures, action was required to allocate appropriate persons to the clinical evaluation of the outcome of these exposures. This is further discussed under Regulations 6 and 10 within this report.

Inspectors were assured that MPE involvement in the service was proportionate to the radiological risk posed by the service, and that the undertaking's management team had good arrangements in place to ensure the continuity of this service in the radiology department. Inspectors also noted that since the previous inspection, the undertaking's management team had implemented appropriate measures to ensure that the MPE team contributed to their allocated responsibilities as set out in Regulation 20.

Notwithstanding some gaps to achieve full compliance with Regulations 6, 10 and 13, inspectors were assured that service users were receiving a safe radiological service at Wexford General Hospital.

Regulation 4: Referrers

The undertaking had allocated the role of referrer to medical practitioners and hospital approved advanced nurse practitioners could also act as referrers for specified general X-ray procedures. Inspectors were also informed that radiographers could make adapted and secondary referrals for medical exposures.

From discussions with staff and a review of a sample of medical exposures records, inspectors were satisfied that only referrals for medical radiological procedures from persons as defined in Regulation 4 were carried out at this service.

Judgment: Compliant

Regulation 5: Practitioners

In Wexford General Hospital, radiographers and radiologists had been allocated the role of practitioner, which is in line with Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

During the inspection of Wexford General Hospital, inspectors were assured that the undertaking had adequate governance and management arrangements in place, which provided oversight of the medical ionising procedures completed in the service. However, inspectors noted that allocation of these roles and responsibilities required improvement, to ensure that the documented arrangements and arrangements in practice clearly aligned, for example in the organogram and *Radiation Safety Procedure* presented to inspectors.

While the management team had allocated many of the roles and responsibilities for the radiation protection of service users in the local *Radiation Safety Procedure*, further action was required to ensure that all such roles and responsibilities were clearly allocated. For example,

- from a review of service user's records on medical exposures, inspectors noted that for a sub-set of fluoroscopy exposures completed in the service, the undertaking had not allocated responsibility for the evaluation of the clinical outcome of the exposure to a practitioner as defined in Regulation 5. This is further discussed under Regulation 10: Responsibilities below
- during discussions with radiography staff in the service, inspectors were informed of the comprehensive measures in place to enquire on the pregnancy status of relevant service users. However, the documentation to support and guide staff in their roles and responsibilities in these processes did not align with the practices completed by them. Therefore, inspectors were not assured that the undertaking had clearly allocated roles and responsibilities around this radiation protection measure

- inspectors were not provided with evidence that the roles and responsibilities for ensuring compliance with Regulation 7: Justification of Practices were allocated in the service

While some improvements were required in documentation of and in the allocation of responsibilities, inspectors were satisfied that overall there were effective arrangements in place to ensure the radiation protection of service users at Wexford General Hospital.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that practitioners and the MPE team were involved in the optimisation of medical exposure to ionising radiation in Wexford General Hospital. From a review of service user records and other documentation, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Inspectors noted that the majority of medical exposures, such as general X-ray, CT and some fluoroscopy exposures, took place under the clinical responsibility of a practitioner. However, from a review of exposure reports, documented roles and responsibilities and from discussions with staff, inspectors found that, for a particular sub-set of fluoroscopy medical exposures, the clinical evaluation of the outcome of these exposures was not carried out. The undertaking must address this gap to ensure that all aspects of clinical responsibility are allocated to a practitioner for all medical exposure procedures, as per Regulation 10(1).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

From discussions with staff and a review of documentation, inspectors were satisfied that there were appropriate arrangements in place to ensure the continuity of medical physics expertise in Wexford General Hospital.

Inspectors were also informed that physics staff, employed in the service, were undergoing MPE training. This was noted as a good example of proactively strengthening the MPE continuity arrangements and the radiation protection of service users in the service.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors observed that MPEs were involved in and contributed to radiological practices and the radiation protection of services users in Wexford General Hospital, and the current professional certification records for the MPEs were reviewed by inspectors on the day of inspection.

A review of documentation and various records showed that the MPE team were involved in the optimisation of medical exposures and contributed to the quality assurance (QA) and acceptance testing of medical radiological equipment. The team had also contributed to the review and approval of local diagnostic reference levels (DRLs) for each piece of equipment, and provided advice and dose calculation for radiation incidents.

Inspectors noted that the MPEs attended and contributed to the RPU and RSC meetings, and were informed that they guided staff to avail of training in the relevant aspects of radiation protection. Inspectors were informed that the MPE team were committed to revising and strengthening these training sessions for all staff involved in the radiology service in the hospital.

Judgment: Compliant

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

From a review of documentation and discussions with staff, inspectors were satisfied that MPE involvement in the medical radiological service of Wexford General Hospital was proportionate to the level of radiological risk in the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

During discussions with staff and a review of documentation, inspectors learned that the undertaking was committed to improving the radiation protection of service users by ensuring that medical radiological procedure doses were kept as low as reasonably achievable. This was achieved, amongst other ways, by the use and regular review of diagnostic reference levels (DRLs), strict surveillance on the

performance of equipment and the analysis and the conduct of clinical audit on many aspects of the radiology service.

From the review of a sample of service user records on medical exposure procedures, inspectors were assured that the management team had implemented appropriate measures to ensure that all medical exposure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Inspectors also noted that, since the previous inspection, the undertaking had made good efforts to ensure that information relating to patient exposure formed part of the medical radiological procedure report. However, as such reports were not available for a sub-set of medical exposures, the undertaking was not yet in full compliance with Regulation 13(2).

A clinical audit strategy had been developed by the undertaking's management team in line with the *National Procedures for Clinical Audit of Radiological Procedures involving Medical Exposure to Ionising Radiation*, which detailed the roles and responsibilities to support the service's clinical audit programme and also identified areas for audit over a three year period. However, during discussions with the management team, inspectors were informed that a number of audits may not be completed as scheduled due to low staffing levels in the radiology department. The undertaking must provide adequate staffing resources to support and implement the services' clinical audit strategy and thereby ensure that safe and appropriate procedures involving medical exposures are delivered to service users.

Inspectors noted that local facility diagnostic reference levels (DRLs) had been established and routinely compared to national levels within the service. Where local DRLs exceeded national levels, records of corrective actions, as agreed by a multidisciplinary team, were available. Inspectors also noted that following the previous inspection, the management team had ensured that paediatric DRLs for general radiography were reviewed annually and compared to national DRLs.

Inspectors was satisfied that the undertaking had systems in place to ensure that all medical radiological equipment was kept under strict surveillance. Records of acceptance and performance testing for all radiological equipment at the facility were available and these assured inspectors that the undertaking's management team had implemented and maintained a comprehensive QA programme.

Since the previous inspection in May 2022, the undertakings' management team had improved the measures to minimise the probability of re-occurrence of significant events, as required by the regulations. For example, inspectors observed that each reported incident was appropriately analysed by appropriate personnel to identify the causes(s) of the incident, and the appropriate corrective actions and lessons learnt. Inspectors were also satisfied that the management team in Wexford General Hospital had arrangements in place to ensure that HIQA was notified of the occurrence of any significant event and comprehensive investigation reports were received by HIQA, which demonstrated a multi-disciplinary approach to incident management. This was identified as an area of good practice in the service.

Overall, while some areas for improvement were noted, inspectors were assured that the undertaking had appropriate systems in place to support the safe delivery of medical exposures at Wexford General Hospital.

Regulation 8: Justification of medical exposures

On the day of the inspection, inspectors reviewed a sample of written referrals for medical exposures and saw that each was in writing and clearly stated the reason for the referral. They also noted that each was accompanied by sufficient medical data to allow the practitioner to consider the benefits and risks of the medical exposure and thereby determine if the procedure was justifiable. From discussions with practitioners and a review of the Radiation Safety Procedure, inspectors were informed that there were systems in place to ensure that medical exposures were justified in advance of being completed by the referrer and practitioner and that the justification decision was recorded.

Information about the benefits and risks associated with the radiation dose from the various medical exposure procedures was available to service users in leaflet format, and inspectors were informed that, when feasible, this information was posted to service users in advance of their appointment, which provided them with sufficient time to consider the risk and benefits associated with the medical radiological procedure.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff about the measures in place to ensure that the medical radiological procedures in the service were optimised. The written protocols for procedures detailed patient and equipment positioning, and the number of image views as optimisation considerations for service users undergoing a medical exposures. The *Radiation Safety Procedure* also clarified the responsibilities of those involved in the optimisation of service users' doses.

Other optimisation measures in Wexford General Hospital included the use of DRLs for both adult and paediatric service users, the implementation of regular quality assurance testing on the medical radiological equipment and the completing of clinical audits in the service.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs had been established for common adult and paediatric radiological procedures completed in Wexford General Hospital. From a review of this DRL data, inspectors noted that most were below national DRLs and that for two procedures, where the 2024 data was found to be slightly above national levels, the evidence showed that the RPU team had undertaken a further review of the gathered data and agreed to collect additional information on these exposures with a view to implementing measures, if necessary, to reduce doses. This continuous monitoring by the management team was identified as an area of good practice in the service.

While in the radiology department, inspectors observed that the most recently established DRL information was displayed in all console areas, and staff who spoke with inspectors demonstrated an awareness of how to use this data when completing medical exposures of ionising radiation.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors noted that written protocols for standard medical radiological procedures had been developed by the management team and were easily accessible to staff in the clinical areas. Inspectors also noted that appropriate referral guidelines were available to staff, for reference during referral and justification processes.

During a review of service user's records, inspectors looked at a sample of medical exposure reports for all imaging modalities available in the service, and found that information relating to the exposure formed part of the report for all exposures other than a particular sub-set of fluoroscopy exposures as required by Regulation 13(2). For this particular sub-set of fluoroscopy exposures, inspectors saw that information relating to patient dose was recorded in a dose log book, which demonstrated some awareness by the management team of monitoring the doses received by this cohort of service users. However, to fully meet the requirements of the regulation, this information must form part of the report on the medical radiological procedure.

The management team had developed a clinical audit strategy in line with the *National Procedures for Clinical Audit of Radiological Procedures involving Medical Exposure to Ionising Radiation*, and a number of clinical audits had been completed in the service, such as audits on referral records, the assessment of dose and practitioner justification records. Inspectors were informed that the results and learning from these audits were available to relevant staff at monthly staff meetings. The RSC was allocated oversight of the clinical audits completed in the radiology service, to ensure that audit results and recommendations were addressed, re-

evaluated and where necessary quality improvement plans implemented and sustained. In addition, the management team had measures in place to ensure that the Wexford General Hospital Clinical Audit Committee were made aware of the radiology department's clinical audit schedule and topics, and that such audits were designed in line with the hospital-wide methodology for clinical audit. This collaborative approach to clinical audit was identified as an area of good practice in the service.

Judgment: Substantially Compliant

Regulation 14: Equipment

From a review of records and meeting minutes, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking's team in Wexford General Hospital. A quality assurance programme had been developed, implemented, maintained and included acceptance and regular performance testing. Records of radiographer and MPE performance testing were reviewed during the inspection, and inspectors saw that all were completed as scheduled. Inspectors were also assured that there was appropriate oversight of the QA programme, with regular update reports provided at the RPU meetings. The MPE team also informed inspectors of a system in place to ensure that required actions and recommendations from QA testing were efficiently completed. This system was identified as an area of good practice in the service.

Prior to the inspection, the undertaking's management team provided inspectors with an up-to-date radiology equipment inventory, which was verified onsite on the day of the inspection.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed that notices were displayed in the waiting areas of the radiology department, to raise awareness of the special protection required during pregnancy with regard to medical exposure to ionising radiation. This information was provided in a number of different languages, which was identified as an area of good practice in the service.

From speaking with staff, inspectors were informed of a number of processes completed by practitioners, to enquire about the pregnancy status of relevant services users, prior to any medical exposures being performed. However, as previously discussed under Regulation 6, the service's *Radiation Safety Procedure*

required review to ensure that it fully aligned with all pregnancy enquiry processes being completed in the department.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors observed that there were arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

The *Radiation Safety Procedure* outlined the roles and responsibilities, and the process for the management of accidental and unintended exposures and significant events. All incidents and potential incidents were recorded on a local incident management system, and as recorded, the RPO and the RSM were notified and subsequently the MPE team. The procedure also stated that reported radiation incidents were reviewed by the hospitals' Clinical Risk Manager. However, at the time of the inspection, this responsibility had been re-assigned to the hospitals' Operations Manager as the Clinical Risk Manager role was vacant.

Although the RSM was responsible for analysing, investigating and trending reported incidents, inspectors were informed that there was multidisciplinary oversight of this information through discussions at RPU and RSC meetings. Inspectors were also informed of a communication pathway for incidents from the Designated Manager to the Undertaking Representative, should this be required.

Inspectors noted that while there was a good culture of incident reporting in the department, there was potential to improve the reporting of near miss events. From the review of an overview report on incidents and near misses in the department, inspectors saw that the number of reported near misses was comparatively low to the number of medical exposure procedures performed annually in the service. As the recording of potential incidents can assist in identifying and implementing corrective actions to improve the radiation protection of service users, the undertaking should ensure that the systems in place appropriately facilitate staff in identifying and reporting potential incidents.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. 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	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Wexford General Hospital OSV-0007382

Inspection ID: MON-0044592

Date of inspection: 18/02/2025

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, as amended.

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: Report template for a video fluoroscopy medical exposure studies to be built on PACS system which clearly outlines that the studies happen under the clinical responsibility of Consultant Radiologist. The report template will include the dose information for each study. (Will be completed in 4 weeks)</p> <p>When deciding the wording for the report template and the arrangements for recording the dose we will take into account the recent guidance issued by the NRPC "Proposal for compliance with Reg 13(2)", April 2025.</p> <p>The RSPs will be updated to explicitly state that a Consultant Radiologist is responsible for the clinical outcome of video fluoroscopy medical exposure studies. (Will be completed in 4 weeks)</p> <p>A PPPG will be drafted in consultation with the Speech and Language Therapy Department which clearly outlines the allocation of responsibilities for video fluoroscopy medical exposures. (Will be completed in 3 months.) This PPPG will then be submitted for approval to the hospital's PPPG Committee.</p> <p>The RSPs will be updated to reflect the Joint IIRRT and IAPM National Pregnancy Policy 2017. (Will be completed in 4 weeks)</p> <p>The RSPs will be updated to introduce a mechanism for reviewing planned changes in practice or introduction of a new practice that may or may not be justified under Regulation 7. (Will be completed in 4 weeks)</p> <p>The organogram detailing the overarching governance and management arrangements of the HSE has been revised in line with guidance recently published by the NRPO. The organogram is enclosed with this response and will be added as an appendix to the RSPs.</p>	

Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: Report template for a video fluoroscopy medical exposure studies to be built on PACS system which clearly outlines that the studies happen under the clinical responsibility of Consultant Radiologist. The report template will include the dose information for each study. (Will be completed in 4 weeks)</p> <p>When deciding the wording for the report template and the arrangements for recording the dose we will take into account the recent guidance issued by the NRPO.</p> <p>The RSPs will be updated to explicitly state that a Consultant Radiologist is responsible for the clinical outcome of video fluoroscopy medical exposure studies. (Will be completed in 4 weeks)</p> <p>A PPPG will be drafted in consultation with the Speech and Language Therapy Department which clearly outlines the allocation of responsibilities for video fluoroscopy medical exposures. (Will be completed in 3 months.) This PPPG will then be submitted for approval to the hospital's PPPG Committee.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: As of March 2025, all information pertaining to medical exposure dose is manually recorded by the radiographer present during the fluoroscopy procedure on the Triple Identification Form. As per RSPs the Triple Identification Form is scanned onto the NIMIS for inclusion onto the patient's permanent record. This will ensure that the information related to the patient exposure is available to the practitioner at the time of writing the medical exposure report and later for audit or inspection purposes. The medical exposure report will include the dose information for each medical radiological procedure.</p> <p>The RSPs will be updated to instruct Radiographers to record dose information on the Triple Identification Form. (Will be completed in 4 weeks)</p> <p>In the interim, an email was circulated to all relevant staff by the RPO on 02/03/2025 stating the above information and was discussed on 16/04/2025 at the Radiographer team meeting.</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	22/07/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	20/05/2025

Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	20/05/2025
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