Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	The National Maternity Hospital
Undertaking Name:	The National Maternity Hospital
Address of Ionising Radiation Installation:	Holles Street, Dublin 2
Type of inspection:	Announced
Date of inspection:	05 December 2023
Medical Radiological Installation Service ID:	OSV-0007411
Fieldwork ID:	MON-0040493

About the medical radiological installation:

The National Maternity Hospital is part of the Ireland East Hospital Group (IEHG) which comprises 11 hospitals in total. There are three other maternity hospitals within the IEHG group with significant interlinking of services and established links with Children's Health Ireland (CHI) (paediatric) and St Vincent's University Hospital SVUH (adult) hospitals. Established in 1894, it is now one of Europe's largest maternity hospitals with 154 inpatient beds. The hospital provides maternity, gynaecology, neonatology, fetal medicine, anaesthetics, pathology, radiology, maternal medicine, perinatal mental health, urogynaecology, National Neonatal Transfer Service and community midwife services. The Neonatal Intensive Care Unit (NICU) is the national referral centre for complicated pregnancies, premature and sick infants and gynaecology services treat over 10,000 patients annually. The radiology department at the National Maternity Hospital provides diagnostic services to adult and neonatal inpatients and outpatients. Imaging service include: ultrasound, general radiography, fluoroscopy and magnetic resonance imaging (MRI). Mobile radiography is carried out in our Neonatal Intensive Care Unit (NICU). A refurbishment of the department in 2020 saw the installation of a digital radiography (DR) system and upgrades to our existing services. NMH is the national fetal MRI referral centre accepting referrals throughout Ireland. The Radiology Department carries out 7000 examinations annually providing a range of, gynae and neonatal imaging.

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[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] 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[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 5 December 2023	09:35hrs to 15:30hrs	Kay Sugrue	Lead
Tuesday 5 December 2023	09:35hrs to 15:30hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

An inspection of the radiology department at the National Maternity Hospital (NMH) was carried out on the 5 December 2023. On the day of the inspection, inspectors reviewed a sample of records and documentation and spoke with staff and management working in this facility.

The NMH was the undertaking with overall responsibility for the radiation protection of service users. A radiation safety committee (RSC) was in place with oversight of matters relating to the radiation protection of service users. Inspectors were satisfied that established communication pathways were effective, to ensure that relevant radiation protection issues were communicated upwards to the board of the NMH and the undertaking as required.

Inspectors reviewed the allocation of responsibilities for the protection of adult and paediatric service users from medical exposures to ionising radiation and were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer. Similarly, only individuals entitled to act as a practitioner took clinical responsibility for medical radiological exposures. A medical physics expert (MPE) was appropriately involved in the service in line with the radiation risk associated with the service delivered in this radiology department. Staff informed the inspectors that the MPE was very accessible either through regular onsite attendances or via phone or email, however, contingency arrangements to ensure the continuity of the MPE service were not evident to inspectors as per Regulation 19(9). This also meant that further action was needed by the undertaking to ensure that all aspects relating to the allocation of responsibilities are in place to comply with Regulation 6(3).

Documentation updates were required to ensure day-to day practices described by staff to inspectors during the inspection were aligned to procedures documented in hospital policy. For example, there was ambiguity evident between documents viewed by inspectors and day-to-day practices described by staff regarding the categorisation and management of carers and comforters who provide support to babies during a medical exposure. Therefore, greater clarity was needed to ensure there is consistency between local policy and practice in relation to this issue. Inspectors also found that the use of duplicate referrals written in advance of a procedure involving the insertion of a central venous catheter in babies should be revisited. The undertaking at the NMH needs to provide assurance that firstly, a duplicate referral written for the same intent and procedure is necessary, and secondly, that all potential risks associated with this process have been considered.

Despite the gaps in compliance identified in this report, inspectors were satisfied that staff working in this facility were committed to the radiation protection of service users with special attention paid towards the protection of its neonatal population from the effects of ionising radiation during medical exposure.

Regulation 4: Referrers

From a sample of records reviewed and from speaking with staff, inspectors were satisfied that referrals for medical radiological exposures were only accepted from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Only those entitled to act as practitioners as per the regulations were found to take clinical responsibility for medical exposures in the radiology department on the day of inspection. Radiographers and radiologists were the practitioners for all medical exposures conducted in this facility.

Judgment: Compliant

Regulation 6: Undertaking

The NMH was the undertaking and had a radiation safety committee (RSC) in place that met twice a year. This committee was chaired by a consultant radiologist who was also the head of the radiology department. Terms of reference and minutes from this committee's meetings, viewed by inspectors, showed there was a multidisciplinary membership including the hospital's general manager or senior management representative, a representative from clinical risk, the MPE, the designated manager and clinical engineering representation. The RSC submitted an annual report to the clinical governance executive committee. The general manager, who was also the undertaking representative, was a member of this committee and provided a direct line of communication to the NMH board and undertaking.

There was a strong emphasis placed by all staff who spoke with inspectors on the importance of radiation protection for all service users with a particular focus on neonates due to the increased vulnerability to the effects of exposure to ionising radiation. The undertaking had ensured that the appropriate staff, as per regulations, were allocated with responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Radiologists and radiographers were the practitioners and referrers were clearly identifiable in all referrals viewed. The undertaking had ensured that an MPE was engaged for the service, however, the lack of contingency arrangements for the continuity of MPE services required further action by the undertaking to comply with

Regulations 19(9). This also impacted compliance with Regulation 6(3) as not all aspects relating to the allocation of responsibility were met.

Staff working in the radiology service were supported in their roles through a suite of policies, procedures, protocols and guidance which were developed by staff working in the radiology department. Staff informed inspectors that there was multidisciplinary input into the revision and development of guidance documentation, however, this input was not documented nor was the management oversight within radiology governance structures evident in documentation viewed. Therefore, inspectors identified that the process to approve radiation protection documentation should be improved and formalised following this inspection. In addition, inspectors identified gaps in documentation as some documents viewed did not consistently reflect practices described to inspectors. For example, there was some ambiguity evident between guidance provided in the document *Radiation safety procedures* and hospital policy and practices described to inspectors regarding the protection of persons who act as carers and comforters to babies undergoing medical exposure to ionising radiation. In addition, the duplicate referral process for the insertion of intravenous central lines in infants described by staff to inspectors was not evident in documentation viewed. Inspectors identified that this process should be revisited to provide greater assurance in relation to the potential risks of inadvertent or accidental exposures associated with duplicate referrals and in consideration of the intent of these duplicate referrals for the same procedure.

While some improvements were required relating to gaps in documentation and the allocation of responsibility, inspectors were satisfied that there was a strong focus placed by staff on the radiation protection of service users in practice at this facility.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

On the day of inspection, inspectors found that overall clinical responsibility for all medical radiological procedures was the responsibility of the consultant radiologists at the NMH. Inspectors also were satisfied that both referrers and those entitled to act as practitioners, were involved in the justification of individual medical exposures. Similarly, inspectors found evidence that practitioners and the MPE were appropriately involved in the optimisation process for medical exposures delivered at the hospital.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Staff informed inspectors that there was appropriate access to the MPE engaged for the hospital who was regularly on site and was also available by phone or email should the need arise. However, inspectors were not satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at the hospital. Management informed the inspectors that they were aware of this gap in compliance and were exploring available options that would adequately address this deficiency.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

From a review of the professional registration certificate of the MPE engaged at the NMH, inspectors were satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

There was evidence provided in documentation viewed and from discussions with staff, including the MPE, to demonstrate that an MPE was involved in, and provided oversight of, matters relating to radiation protection at this facility. Inspectors were satisfied that the MPE was involved in the quality assurance and performance testing of medical radiological equipment, dosimetry and the review and approval of DRLs. Inspectors were informed that the MPE was very accessible to staff and was on-site once a month and attended the RSC meetings. Staff informed inspectors that the MPE received regular updates on all radiation incidents and near misses that occurred at the facility and also contributed to staff training on radiation protection.

The MPE was also the radiation protection advisor (RPA) in this facility thereby meeting the requirements set out in Regulation 20(3).

Judgment: Compliant

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

The inspectors were satisfied that the MPE was appropriately involved at the NMH, with the level of involvement proportionate with the radiological risk posed by the service delivered at this facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the radiation protection of service users undergoing medical exposure to ionising radiation and found there were multiple systems in place to ensure the safe delivery of medical exposures at this facility. Inspectors found that the undertaking was compliant with Regulations 8, 9, 11, 15, 16 and 17, with action needed by the undertaking to comply with Regulations 13 and 14.

From documentation reviewed and discussions with staff, inspectors were satisfied that justification in advance was carried out for each medical radiological procedure by a practitioner and this record was evident on the radiology information system. Referral records viewed were in writing and detailed sufficient medical data relevant to the procedure requested. In relation to Regulation 16, the radiation protection of pregnant woman undergoing medical exposure to ionising radiation was strongly emphasised by staff and inspectors found there were effective processes in place for the justification and re-justification of these medical exposures.

Diagnostic reference levels (DRLs) were evident and available for staff to reference when carrying out medical exposures therefore, meeting the requirements of Regulation 11(5). Staff informed inspectors that they not only compared facility DRLs to national DRLs but also compared these levels with other maternity hospitals in the region who have similar equipment. This was found by staff to be beneficial as a standard of comparison, particularly for examinations that do not have a national DRL, and offered further assurance regarding the optimisation of the radiation doses received by patients.

Inspectors identified areas of good practice in clinical audit that looked to optimise medical exposures with special attention focused on the neonatal population. For example**,** through audit findings and measures implemented, the number of unjustified neonatal skull X-rays had been significantly reduced at the hospital. Good practices were also observed in relation to the system and processes to identify, record, analyse and manage radiation incidents and near misses.

Some areas of improvement were identified during this inspection. For example, inspectors found that relevant daily quality control checks, as recommended by the manufacturer of the medical radiological equipment, should be implemented as part of the quality assurance (QA) programme to ensure the strict surveillance of equipment required under Regulation 14. In relation to Regulation 13(2), the undertaking at NMH must ensure that compliance measures are implemented at the hospital to meet the requirements of this regulation.

Despite the improvements required with respect of Regulation 13 and 14, overall, inspectors were satisfied that the hospital had systems and processes in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referrals for medical radiological procedures performed at the NMH. All referrals reviewed were in writing, with the reason for the request and sufficient clinical data evident to facilitate justification by a practitioner.

Inspectors found that justification of medical exposures was performed by a practitioner in all examples viewed and a record of justification was evident on the hospital's radiology information system as per the regulations. However, while compliant with Regulation 8, the manner in which justification was recorded could be better aligned to the practitioner who carried out the procedure and justification and therefore should be considered as an area for improvement**.**

Inspectors were informed that information leaflets were given to service users to provide information relating to the benefits and risks associated with the examination and posters with similar information were observed by inspectors in the waiting areas in the radiology department.

Judgment: Compliant

Regulation 9: Optimisation

From discussions with staff and a review of documentation, inspectors were satisfied there were appropriate processes in place to ensure that the doses delivered for each individual medical exposure to ionising radiation were kept as low as reasonably achievable (ALARA) consistent with the intended outcome.

The hospital had a policy titled *Optimisation of medical radiation exposures* which was approved in November 2023. This document detailed the steps to be taken before and during each procedure to ensure the requested examination was justified and to ensure that the correct neonate, paediatric or adult exposure parameters were used as part of the optimisation process. It was clear to inspectors following discussions with staff, that established DRLs were available to staff when carrying out X-rays and were attached to mobile X-ray machines or in the X-ray room to reference as required. Inspectors were informed that staff attended a tri-hospital forum where reference levels were compared across sites to ensure consistency in the standard of care. This was seen by staff as a useful exercise, particularly, in the context of limited national DRLs available for comparison for neonatal and paediatric procedures. Staff informed inspectors that the installation of new medical radiological equipment in 2020 had contributed to the reduction of doses to service users.

Inspectors also noted examples of good practice in clinical audit with the aim of improving optimisation of medical radiological procedures for neonates and babies which are discussed further under Regulation 15. Inspectors were also informed that there was a strong emphasis placed on considering alternative techniques with the

same objective using no or less exposure to ionising radiation. Consequently, the number of radiographs has decreased with a preference towards the modalities of ultrasound and magnetic resonance imaging (MRI) where relevant, or in some cases, photography and direct referral to a cranio-facial specialist to reduce the need for unnecessary neonatal skull X-rays.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The NMH had a policy titled *Diagnostic Reference Levels* which was updated in November 2023. Staff confirmed to the inspectors that the radiation safety officer who was also the designated manager, had responsibility for collating data to establish DRLs which were then approved for clinical use by the MPE. In addition, inspectors were informed that facility DRLs were compared with available national DRLs and as discussed under Regulation 9 also shared and compared with other sites with similar equipment. The evidence gathered demonstrated compliance with this regulation.

Judgment: Compliant

Regulation 13: Procedures

Inspectors were satisfied from a review of documentation that protocols were available for each standard radiological procedure provided in this facility as per the regulations. Referral guidelines were available for staff and referrers as required by Regulation 13(3).

Inspectors saw evidence of clinical audit, examples of which are detailed under Regulation 15 and demonstrated that staff used audit as a tool to identify areas of improvement in the referral and justification of procedures, with a particular focus on minimising the risks associated with the exposure to ionising radiation of its neonatal population.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors found from the reports of medical radiological procedures viewed and from discussions with management and staff, that there was a lack of evidence to demonstrate compliance with this regulation. Staff informed inspectors that this gap in compliance had been identified and measures that would facilitate compliance were under review. Following this inspection, the undertaking for the NMH must

ensure that compliance measures are implemented at the hospital to meet the requirements of Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in use at the NMH which was verified during the inspection. Equipment listed in this inventory was installed in 2020 and records viewed demonstrated that acceptance testing on these units had been completed before first clinical use in line with Regulation 14(3)(a).

Inspectors were satisfied that annual quality assurance and quarterly performance testing were completed in line with the quality assurance programme in place. There was also evidence of a process in place to report any equipment faults or emerging issues if required. However, from the records reviewed, inspectors found that the daily quality control checks recommended by the manufacturers of the medical radiological equipment in use had not been included in the QA programme or implemented. Staff informed inspectors that some daily checks were undertaken but these were not routinely documented. Inspectors did not identify any issues relating to the performance of the equipment and were satisfied that the deficiencies found regarding daily checks did not pose a radiation risk to paediatric service users at the time of the inspection. However, to ensure that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection, the undertaking should review the QA programme to ensure that daily quality control checks are carried out as per the manufacturer's recommendations to comply with Regulations 14(1), 14(2)(a) and 14(3)(b).

Judgment: Substantially Compliant

Regulation 15: Special practices

Inspectors found strong evidence to show that there was special attention placed on the assessment and verification of dose for babies undergoing medical exposure to ionising radiation at the NMH. Staff described numerous measures taken to ensure the justification and optimisation of medical exposures undertaken at the hospital. For example, there was a strong emphasis on the use of alternative imaging where possible to achieve the diagnostic intent that did not involve ionising radiation. Staff informed inspectors that doses to service users were kept as low as reasonably achievable and emphasised the importance of positioning, collimation and applying the correct exposure parameters when carrying out medical exposures on paediatric

service users. In addition, since the move to digital radiography (DR) systems in 2020, inspectors were informed that there had been an 18% reduction in DRLs.

Results of an audit of the justification of skull X-ray referrals in neonates were shared with referrers and practitioners with recommended measures to be implemented. A follow up audit found there was a 50% reduction in neonatal skull X-rays which was achieved by stronger justification practices and the use of photo images as an alternative to skull X-ray for direct referrals to a cranio-facial specialist located in another facility.

Staff informed inspectors there was a cross-site forum in place to share information with staff working in other maternity hospitals in the Dublin area which was described as very beneficial. Topics discussed included the sharing of information regarding diagnostic reference levels, equipment issues, regulatory compliance, medical radiological practices specific to neonates and development of local policy. Inspectors were informed that a cross-site audit was underway within this forum that was monitoring every chest X-ray performed for the paediatric population. The aim of this audit was to standardise paediatric chest X-rays to ensure the optimisation of doses delivered were aligned to established parameters with good diagnostic image quality and offered a good way to share learning.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors observed posters in the service user waiting area, including multilingual posters, with the aim of increasing the awareness of women to whom this regulation applied.

The hospital policy *Protection of unborn child arising from radiation during medical radiation exposures* detailed the process in place to determine the pregnancy status of relevant service users which was consistent with the practice described by staff to inspectors. Staff described the practitioner role in ruling out pregnancy prior to any planned medical exposure including the special attention given to the re-justification of examinations for pregnant women undergoing a medical radiological procedure. Records confirming that pregnancy enquiries were made by a practitioner were viewed by inspectors on the hospital radiological information system, thereby demonstrating compliance with this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The policy document *Notification of ionising radiation incident in radiology* viewed by inspectors outlined the procedure for staff to manage and record notifiable significant events, non-notifiable radiation incidents and near misses. To aid staff in identifying the types of events that may occur, an example of each one of these events was provided in this policy along with frequently asked questions and answers on what to do should an incident occur. Inspectors were satisfied from discussions with staff and documentation review that analysis of reported incidents resulted in actions taken to minimise potential risks and recurrences. Overall, inspectors found from the evidence gathered, that the undertaking met the requirements of this regulation.
Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
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	Not 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	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for The National Maternity Hospital OSV-0007411

Inspection ID: MON-0040493

Date of inspection: 05/12/2023

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
Outline how you are going to come into compliance with Regulation 6: Undertaking: We will review our radiation safety procedures and adjust as negligible risk to clarify our practice in clinical holding in general x-ray and fluoroscopy, in the small number of cases where this may be required. Similarly, we will address the issues raised with regard to the 'duplicate referral processes and resolve to amend in the clinical referral policy. Contingency arrangements for MPE services outlined in regulation 19(9) will aim to fully comply with regulation 6(3) addressed in Regulation 19(9). S- Radiation safety procedures updated with MPE to clarify our practice in clinical holding. Address the 'duplicate referral' practice with change reflected in policy. - Distribution in hard copy policy and team meetings. A- Updated to address changes recommended at inspection. R- This is a realistic objective and will provide clarity on our current processes. T- These recommendations will be fully implemented by 31.03.24	
Regulation 19: Recognition of medical physics experts	Not Compliant
Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:	

We recognise the issue raised in relation to the continuity of MPE cover. The hospital will review the model for MPE/RPA provision to ensure adequate continuity of MPE support. We propose transitioning to the provision of MPE support from a larger medical service. Our current MPE will support the transition with the aim to have contingency in place by 30.06.24.

S-Undertaking review of MPE support to ensure continuity of cover to fully comply with Regulation 19.

M- Expression of interest in progress to transition for provision of MPE support from a larger medical service, with full support from current MPE.
Arrangements for short term interim cover in progress to fulfil compliance with Regulation 19.

A- The hospital recognises the issues raised at inspection and will explore all options available to provide continuity of MPE cover.

R- The hospital recognises that continuity of MPE is a priority for compliance with Regulation 19.

T- The hospital aims to have contingency in place by 30.06.2024

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
We have implemented the exposure information with approved script on the examination reports. We are aware that that this was a recent addition to our reports and was not available on the prior reports viewed on the day of inspection.

S- Implementation of exposure information on the examination report for compliance with Regulation 13.

M- The defined approved script is available on current examination reports. A detailed examination dose page is further available as part of each study performed.

A-This solution is implemented in other sites for compliance.

R- This is a realistic objective and required technical implementation to our PACS system.

T- This is complete and in effect at present

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
We have reviewed our QA procedures and incorporated the daily QC checks consistent with the manufacturers' recommendations.

S- Addition of daily and monthly QA checks to equipment to fully comply with Regulation 14(1), 14(2) (a) and 14(3) (b).

M- Results are logged online as part of QA programme.

A-This is a realistic objective and in place as part of daily radiographer tasks.

T-This is complete and in effect at present.

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/03/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical	Not Compliant	Orange	10/02/2024

	radiological procedure.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	10/02/2024
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	10/02/2024
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.	Substantially Compliant	Yellow	10/02/2024
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Not Compliant	Orange	30/06/2024