



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Royal Victoria Eye and Ear Hospital
Undertaking Name:	Royal Victoria Eye and Ear Hospital
Address of Ionising Radiation Installation:	Adelaide Road, Dublin 2
Type of inspection:	Announced
Date of inspection:	10 November 2022
Medical Radiological Installation Service ID:	OSV-0007484
Fieldwork ID:	MON-0037518

About the medical radiological installation:

The Royal Victoria Eye and Ear Hospital provides ultrasound and radiography (X-ray) imaging services to in-patients and out-patients, as well as to patients attending the emergency department. The hospital has both fixed and mobile direct radiography (DR) equipment. The majority of X-ray procedures carried out at the hospital are chest radiographs. A cone-beam computed tomography (CBCT) has been installed but is not yet operational. Cross-sectional imaging is currently provided at other hospitals in Dublin.

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 10 November 2022	09:00hrs to 16:00hrs	Kirsten O'Brien	Lead

Governance and management arrangements for medical exposures

An inspection of the Royal Victoria Eye and Ear Hospital was carried out on the 10 November 2022 to assess compliance against the regulations. As part of this inspection, the inspector visited the general radiography (X-ray) area at the hospital. On the day of inspection, local governance and management arrangements in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital were reviewed by the inspector.

The Royal Victoria Eye and Ear Hospital was established by a charter and is governed by a hospital council. The inspector found that the clinical director of the hospital was the designated manager and undertaking representative. The hospital's radiation safety committee (RSC) was found to be the main forum for providing oversight to senior management regarding the radiation protection of service users at the hospital and reported up to the quality and safety executive committee. The quality and safety executive committee reported up to the quality and safety subcommittee of the hospital council.

The membership of the RSC included representation from individuals involved in the conduct of medical exposures at the hospital, the designated manager and hospital chief executive officer (CEO), as well as other relevant departments. Terms of reference and minutes for the RSC were reviewed by the inspector who also spoke with staff and management. Although, the terms of reference stated that the RSC should meet a minimum of twice a year, the minutes of the last three RSC meetings reviewed by the inspector indicated that the RSC had met in December 2020, October 2021 and March 2022.

The inspector was satisfied that the hospital had appropriately allocated all aspects of clinical responsibility for medical radiological procedures to 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, practitioners and a medical physics expert (MPE) were found to be involved in optimising medical exposures. The hospital also had appropriate arrangements in place to ensure the continuity of medical physics expertise and appropriate involvement of a medical physics expert (MPE) in line with the radiological risk associated with medical exposures carried out at the hospital.

However, on the day of inspection the inspector was not assured that appropriate governance and management structures were in place to ensure compliance with all requirements of the regulations at the Royal Victoria Eye and Ear Hospital. In particular, the inspector found that the hospital had not ensured that the day-to-day operational aspects of radiation protection were clearly allocated and carried out. In addition, the inspector was informed that the hospital had relied on locum and part-time radiography staff to maintain the X-ray imaging service at the hospital for a number of months. This lack of sustainable structures and continuity of staff was found to be a possible contributory factor to the non-compliances identified on the

day of inspection

Overall, although the inspector was assured that practitioners took clinical responsibility for medical radiological procedures, the lack of a dedicated person clearly allocated administrative and managerial responsibility for important aspects of radiation protection meant that requirements of these regulations were not met on the day of inspection. The Royal Victoria Eye and Ear Hospital, as the undertaking, must ensure that a clear allocation of responsibility for all aspects of the radiation protection of service users is in place to ensure compliance with the regulations.

Regulation 4: Referrers

A sample of referrals for medical radiological procedures were reviewed on the day of inspection. The inspector also spoke with staff and reviewed documentation and was satisfied that only referrals from those entitled to act as a referrer as per the regulations were carried out at the hospital.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of documentation and a sample of records, and from speaking with staff and management, the inspector found that only those entitled to act as practitioners took clinical responsibility for medical exposures at the Royal Victoria Eye and Ear Hospital.

Judgment: Compliant

Regulation 6: Undertaking

On the day of inspection the governance and management arrangements for medical exposures at the Royal Victoria Eye and Ear Hospital were assessed to determine if a clear allocation of responsibility for the radiation protection of service users was in place.

From speaking with staff and management and reviewing documentation available, the inspector found that the Royal Victoria Eye and Ear Hospital was established by a charter and is governed by a hospital council. The designated manager and undertaking representative was the clinical director who sits on the hospital council and RSC. The RSC reported to the quality and safety executive committee. The

quality and safety executive committee was responsible for managing the day-to-day quality and safety issues and reported into the quality and safety subcommittee of the hospital council. The agenda and terms of reference for the quality and safety executive were reviewed on the day of inspection. The inspector found that radiation protection was not a standing agenda item but management communicated that any issues of note were discussed as needed. The terms of reference for the RSC and the minutes of meetings were reviewed by the inspector and the RSC was found to be the main forum for providing oversight to senior management regarding the radiation protection of service users at the hospital. However, the minutes of the last three RSC meetings were provided to the inspector in advance of the inspection and indicated that the RSC had met in December 2020, October 2021 and March 2022.

The inspector was satisfied however that the allocation of clinical responsibility was clearly outlined in the documentation with regards to the groups of professions who could act as practitioners and carry out medical radiological procedures at this hospital. Similarly, those entitled to act as referrers were clearly documented. This provided an assurance that the appropriate individuals carried out and took clinical responsibility for medical exposures at the Royal Victoria Eye and Ear Hospital. A service level agreement was also in place to ensure that an MPE is available to provide consultation and advice on matters relating to radiation physics at the hospital.

The inspector was informed that the radiography service had been staffed by locum and part-time radiographers for a number of months, and as a result, the commencement of a new cone-beam computed tomography (CBCT) service at the hospital was postponed due to staff resource issues. A clear line management structure and pathway for radiography staff to report upward to management at the hospital was also not evident on the day of inspection. The inspector found that the absence of structures to ensure that the day-to-day operational aspects of radiation protection are clearly allocated and carried out contributed to findings of non-compliance with the regulations on the day of inspection. For example, the hospital had not ensured that a schedule of routine performance testing of medical radiological equipment had been implemented for the new general X-ray equipment.

The inspector spoke with staff and management, and reviewed the hospital's documentation and policy, regarding the allocation of responsibility for recording and closing out on accidental and unintentional events involving medical radiological procedures. The hospital's *Policy and Procedure for Incident Management* identified that a head of department/ward manager, or the risk, health and safety manager if allocated, was the incident owner and the person responsible for following up on any issues or incidents. In the absence of an administrative head of department, as was found to be the case for medical exposures to ionising radiation at the hospital, the *Radiation Safety Procedures* specified this should be a nominated consultant. However, the inspector was informed, and observed from a review of incident records, that responsibility for investigating and managing any incidents involving medical exposures was assigned to the radiographer who reported the incident. The process for managing a potential or actual event involving an accidental or unintended exposure to ionising radiation was also described by staff, however the

process communicated differed to the hospital's documented process.

The Royal Victoria Eye and Ear Hospital must review the allocation of responsibilities to ensure that all aspects of the radiation protection of service users are appropriately and clearly allocated to ensure compliance with the regulations.

Judgment: Not Compliant

Regulation 10: Responsibilities

On the day of inspection all medical exposures were found to take place under the clinical responsibility of a practitioner. Those entitled to act as practitioner and the MPE were involved in the optimisation process for medical exposures at the hospital. Similarly, the hospital had measures in place to ensure that the referrer and the practitioner were involved in the justification of individual medical exposures. Additionally, only those entitled to act as practitioners carried out the practical aspects of medical radiological procedures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector spoke with staff and management, including an MPE and reviewed documentation and other records on the day of inspection. The Royal Victoria Eye and Ear Hospital had a service level agreement in place which provided an assurance that necessary arrangements were in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The Royal Victoria Eye and Ear Hospital had a service level agreement in place on the day of inspection which ensured that a MPE was available to act or give specialist advice on matters relating to radiation physics as required by the regulations. The service level agreement outlined the responsibilities and duties of an MPE.

The inspector reviewed documentation and records, and spoke with staff and found that an MPE took responsibility for dosimetry and gave advice on medical radiological equipment. An MPE was also found to contribute to optimisation,

including the application and use of DRLs, the definition and performance of quality assurance, acceptance testing and the analysis of events involving, or potentially involving, accidental or unintended medical exposures.

Judgment: Compliant

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

From speaking with staff and reviewing documentation and other records, the MPE was found to be appropriately involved in line with the radiological risk at the hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures at the Royal Victoria Eye and Ear Hospital. The inspector also reviewed a sample of records of medical radiological procedures and found that information relating to patient exposure formed part of the report of the reviewed records.

All referrals reviewed on the day of inspection were in writing and stated the reason for the request. Staff communicated to the inspector how practitioners justified each individual referral in advance and how this was recorded in writing. However, one record reviewed by the inspector did not have justification in advance documented. Additionally, the inspector found that the method for recording justification in advance was different depending on how the referral was submitted to the hospital and was not always recorded in line with the hospital's policies and procedures. The inspector also found that the hospital did not have sufficient measures in place to ensure that service users were provided with adequate information about the benefits and risks associated with medical exposures prior to the procedure being carried out.

The inspector reviewed documentation and other records relating to DRLs and written protocols for standard radiological procedures and found that policies and other documentation reviewed was for the medical radiological equipment in use at the hospital prior to May 2022 and had not been updated to reflect the subsequent installation of new equipment. Similarly, medical radiological equipment at the Royal Victoria Eye and Ear Hospital was not kept under strict surveillance regarding radiation protection. On the day of inspection, an appropriate quality assurance programme, which included routine performance testing had not been implemented

for the general X-ray and new mobile X-ray equipment.

The hospital's policies relating to special protection during pregnancy were reviewed and staff communicated to the inspector, the process for inquiring about patients' pregnancy status, where required, and how this information was recorded.

However, the record of inquiry into the pregnancy status of one patient was not available for review when requested by the inspector on the day of inspection.

Additionally, the method for recording the outcome of the inquiry into the pregnancy status was found to not align with hospital policy. The inspector was informed that staff currently working in the hospital had only recently been given access to the shared drive which contained the hospital's policies and forms.

Overall, a number of non-compliances with the regulations at the Royal Victoria Eye and Ear Hospital were identified on the day of inspection. The Royal Victoria Eye and Ear Hospital, as the undertaking, must address these gaps to ensure compliance with the regulations.

Regulation 8: Justification of medical exposures

Records and other documentation, including a sample of records of medical radiological procedures were reviewed by the inspector. The inspector also communicated with staff and management to assess how medical exposures were justified in advance by a practitioner to ensure that only medical exposures that show a sufficient net benefit were carried out at the hospital in line with the requirements of the regulations.

All referrals for medical exposures reviewed on the day of inspection 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. Staff communicated to the inspector how the practitioner carrying out the medical radiological procedure took the information provided into account and satisfied themselves that it was justified.

However, the inspector noted that the process for recording justification in advance of an individual medical radiological procedures was different depending on the method of referral and, as a result, did not always align with hospital policy. Staff who spoke with the inspector were also not fully aware of the different methods for practitioners to record justification in advance. Additionally, from reviewing a sample of records, the inspector noted the record of justification in advance was not available for one medical radiological procedure. The Royal Victoria Eye and Ear Hospital must review its documentation and processes for the justification of individual medical exposures in advance to ensure these are accurate and align with day-to-day practice to ensure full compliance with this regulation.

On the day of inspection, the inspector spoke with staff about the process for providing information about the benefits and risks associated with the radiation dose from medical exposures prior to a medical radiological procedure taking place. While

walking around the department the inspector observed that no information about the benefits and risks associated with the radiation dose from medical exposures was available to patients or other service users prior to entering the X-ray examination room. However, a poster which contained information about the radiation dose was located in the X-ray room but this was behind the X-ray table. Given the positioning of this poster within the room it did not provide patients or other service users with an opportunity to adequately review and consider this information prior to their medical exposure. One staff member communicated to the inspector that this information was provided verbally prior to a medical exposure, as needed. As an area for improvement, and to ensure that the hospital is fully compliant with the requirements of this regulation, the hospital should review the measures in place with a view to improving service users access to information relating to the risks and benefits associated with the radiation dose prior to their medical radiological procedure.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The inspector reviewed documentation and other records and spoke with staff regarding the establishment, regular review and use of DRLs at the Royal Victoria Eye and Ear Hospital. DRLs had been established in March 2022 for the most commonly performed medical radiological examinations at the hospital following an annual dose audit. The inspector was also informed by staff that DRLs were reviewed on an annual basis.

However, since March 2022, with the exception of one mobile X-ray machine, new equipment had been installed and was in use at the hospital. While staff communicated that the radiation doses delivered by the new equipment were monitored, based on the evidence available on the day of inspection, the inspector was not satisfied that the hospital had carried out, or begun to carry out, a review of local facility DRLs for the fixed general X-ray equipment which had been installed five months previously. Although the inspector noted that patient numbers may currently be too low to review all local facility DRLs on all pieces of equipment, the hospital should assess the data available since the installation of the equipment and subsequently, for the most commonly performed examinations, for example, chest X-rays, a review of the DRLs should be instigated. This will provide an assurance that the radiation dose for medical radiological procedures is appropriate and has been compared with national values where possible.

The inspector observed that DRLs were available to staff in hard copy and was informed by radiography staff that DRLs, including the national DRLs, were currently used in the department. This was recognised as a positive attempt by the hospital to facilitate the use of DRLs until such time as local facility DRLs are reviewed and updated to reflect the current medical radiological equipment in use in the

department.

Judgment: Not Compliant

Regulation 13: Procedures

The inspector reviewed written protocols available in the general X-ray clinical area. Two different versions of these protocols were available and the protocols contained information specific to the hospital's old X-ray equipment. The inspector also noted hand-written updates had been added to these protocols. Staff communicated to the inspector that they were unsure which version of the written protocols was the most recent. The hospital should review these protocols with a view to ensuring they are up to date for every type of equipment in use at the hospital.

On the day of inspection the inspector found that two audits had been carried out in the last 12 months. One of the audits conducted at the hospital was an annual dose audit which evaluated local facility DRLs and compared these values over a number of years and with available national DRLs. As some medical radiological procedures conducted in Royal Victoria Eye and Ear Hospital can be specialist in nature, national DRLs may not be available for all procedures. Therefore an annual audit of doses received by patients, such as this, is an example of good practice which can help ensure that procedures are optimised and adhere to the as low as reasonable achievable (ALARA) principle. The second audit was an evaluation of the referral process at the hospital using a bespoke imaging application. This imaging application incorporated a clinical decision support tool which provided an assurance that the hospital had arrangements in place to ensure referral guidelines were available to referrers. The use of referral guidelines provides an assurance for the hospital that referrals for medical exposures carried out are for the most appropriate medical radiological procedure taking into account the associated radiation dose.

The inspector also reviewed a sample of medical radiological procedures and found that information relating to patient exposure formed part of the report of those reviewed.

Judgment: Substantially Compliant

Regulation 14: Equipment

On the day of inspection, records and other documents were reviewed and the inspector spoke with staff, management and an MPE. The inspector found that acceptance testing by an MPE had been carried out for the medical radiological equipment at the hospital. The inspector also saw evidence that the equipment

manufacturers had also performed servicing and preventative maintenance recently. Furthermore, an up-to-date inventory of medical radiological equipment was provided to HIQA in advance of the inspection when requested.

The hospital had a policy titled *Equipment Management and Quality Control Plan within the Radiology Department* and this was reviewed by the inspector. This document had not been updated to include the new medical radiological equipment currently in use at the hospital and the associated testing requirements. In addition, on the day of inspection, the Royal Victoria Eye and Ear Hospital had not fully established and implemented an appropriate quality assurance programme for medical radiological equipment in use at the hospital. In particular, a programme and schedule for performance testing on a regular basis had not been established for the hospital's medical radiological equipment. Likewise, while the inspector found evidence that a programme of assessment of dose had been in place for previous equipment, measures to ensure this was maintained for the new equipment were not fully implemented on the day of inspection.

Overall, the inspector was not satisfied that the undertaking had measures and structures in place to ensure that medical radiological equipment was kept under strict surveillance regarding radiation protection. While noting the mitigating elements of quality assurance that had been carried out, the hospital must take steps to ensure that an appropriate and comprehensive quality assurance programme, incorporating all necessary elements is implemented and maintained to ensure that its medical radiological equipment is kept under strict surveillance.

Judgment: Not Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The inspector also reviewed the hospital's policies relating to special protection during pregnancy which was provided to the inspector in advance of the inspection. This documentation was also available on the hospital's shared computer system to facilitate staff access.

On the day of inspection, staff communicated to the inspector the process for inquiring about patients' pregnancy status. The inspector also reviewed a sample of records while in the radiology department and found that the record of the inquiry regarding pregnancy status for the particular patient requested was not available for review at the time of inspection. The written record of an inquiry for a different patient which was in hard copy, was provided to the inspector for review instead. The inspector found that while an inquiry had been made and the answer recorded in writing by a radiographer, it was not recorded using the hospital's form for pregnancy status inquiries, as per hospital policy, or retained as part of the patient records.

The inspector also became aware that staff currently working at the hospital had

only been given access to the shared drive which contained these policies and forms following the announcement of this inspection. Staff did however provide an assurance to the inspector that since gaining access to the shared computer system the forms now used were aligned with the requirements of the hospital's policy.

While the inspector did note that there was signage in the X-ray room and the changing room, no signs or other notices about the special protection during pregnancy and breastfeeding were observed in the waiting room on the day of inspection. As an area for improvement to come into full compliance with this aspect of the regulations, the hospital should review the location of its notices about special protection during pregnancy to ensure they are appropriately placed in public places, for example, the X-ray waiting area.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

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

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Not Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant

Compliance Plan for Royal Victoria Eye and Ear Hospital OSV-0007484

Inspection ID: MON-0037518

Date of inspection: 10/11/2022

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	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <ol style="list-style-type: none"> 1. Radiation protection will be added as a standing agenda item on the quality and safety executive committee and radiation safety committee minutes will be sent to the committee. This will be implemented at the next meeting. 2. A meeting of the Radiation Safety Committee (RSC) was held on 14/12/2022 and next one is scheduled for March 29th 2023. Meetings will be scheduled going forward to ensure terms of reference are complied with. 3. A WTE equivalent Senior Radiographer is due to commence employment in RVEEH on January 2023. They will be supported by a 0.4 WTE Senior Radiographer who has commenced employment recently. Going forward these radiographers will report to the Chief Operating Officer (COO). The COO will also join the RSC. The COO will be briefed on her responsibilities in relation to radiation protection by the Clinical Director and other members of the RSC. CBCT service will commence once all training is complete and procedures and associated QA program is in place. 4. The radiation safety procedures (RSPs) and the departmental operational protocols will be updated to include new reporting arrangements and revised roles and responsibilities. 5. The RSPs will also be revised in relation to incident management so it is aligned with the hospital policy for incident management to ensure incidents are managed by COO. 6. The radiographer induction policy will be updated. 	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <ol style="list-style-type: none"> 1. An email has been sent to all radiography staff re-iterating the importance of 	

recording the fact that the justification is checked in advance of the carrying the exposure. Compliance with this will be audited at the end of the first quarter 2023.

2. The Poster informing patients of the risks associated with medical exposures has been relocated back to its previous location in the waiting room on. Laminated versions in leaflet format will be made available for patients to read in the waiting room

3. The RSPs will be revised to reflect current practice and to include:

- Process of justification of individual medical exposures (written and electronic)
- Scheduling of referrals and justification of general radiographs
- Accepting, scheduling and justification of referrals for CBCT

The RSPs will be signed off at the next RSC on 29th of March.

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

1. An audit has been carried out of DAPs for medical exposures carried out on the general system in December 2022. However given the patient throughput, there is insufficient data to generate DRLs. Interim median DAPs are well within national DRLs and are similar to previous LDRL, (expected given the detector and protocols are very similar). This will be re-audited.

2. Both local and national DRLs are posted at the Radiographers base, an as part of the post exposure checks radiographer review DAP and compare with these DRLs.

Regulation 13: Procedures	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:

1. A plan is in place to revise all protocols so that they reflect the current practice, relevant stakeholders, legislation and equipment. It is planned that all procedures will be reviewed and approved prior to the next RSC meeting on 29/03/2023.

Regulation 14: Equipment	Not Compliant
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Outline how you are going to come into compliance with Regulation 14: Equipment:

1. The policy entitled Equipment Management and Quality Control Plan within the Radiology Department will be updated to include new equipment inventory and new QC program and associated changes, this will be reviewed and approved by 1/2/2023.
2. A quality assurance programme has been implemented for daily and monthly tests for the general system. A replacement test tool for light beam alignment has been ordered. Once received, this test will be implemented monthly.
3. A QC program will be set up and implemented in January 2023 for the X mobile.

Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
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Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:

1. Printed copies of the RVEEH pregnancy status are now available. All staff have been reminded of the hospital's policy in relation to women of child bearing age undergoing medical exposures.
2. A notice about the special protection during pregnancy and breastfeeding has been placed in the waiting room.

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.	Not Compliant	Orange	01/02/2023
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	01/02/2023

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(13)(a)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that the patient or his or her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Substantially Compliant	Yellow	01/02/2023
Regulation 8(13)(b)	Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that in the case of a patient who is under sixteen years of age, a parent or legal guardian of the patient is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.	Substantially Compliant	Yellow	01/02/2023
Regulation 8(13)(c)	Wherever practicable and	Substantially Compliant	Yellow	01/02/2023

	<p>prior to a medical exposure taking place, the referrer or the practitioner shall ensure that in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.</p>			
Regulation 8(15)	<p>An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.</p>	Substantially Compliant	Yellow	01/02/2023
Regulation 11(5)	<p>An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed</p>	Not Compliant	Orange	01/02/2023

	and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	29/03/2023
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Orange	01/03/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Orange	01/03/2023
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Substantially Compliant	Yellow	01/03/2023
Regulation 14(3)(b)	An undertaking shall carry out the following testing on its medical radiological equipment,	Not Compliant	Orange	01/03/2023

	performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.			
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	01/02/2023
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	01/02/2023
Regulation 16(4)	Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to	Substantially Compliant	Yellow	01/02/2023

	increase the awareness of individuals to whom this Regulation applies, through measures such as public notices in appropriate places.			
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