



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:	13 September 2023
Medical Radiological Installation Service ID:	OSV-0007484
Fieldwork ID:	MON-0038478

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
Wednesday 13 September 2023	09:00hrs to 15:00hrs	Margaret Keaveney	Lead

Governance and management arrangements for medical exposures

During an inspection of the radiological service at Royal Victoria Eye and Ear Hospital, the inspector visited the general radiography room and spoke with staff, to monitor the service's ongoing compliance with the regulations and to follow up on compliance plan actions from the previous inspection in November 2022. Overall, the inspector was 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, further action was required under Regulations 6, 8 and 14 to improve compliance with these regulations. This is further discussed throughout the report.

Royal Victoria Eye and Ear Hospital is the undertaking for the Royal Victoria Eye and Ear Hospital, which was established by a charter and is governed by a hospital council. The undertaking's management team had established a radiation safety committee (RSC), which was scheduled to meet twice yearly and the inspector saw that it had done so in the previous 12 months. The inspector also reviewed the terms of reference for this committee and noted that it had a multi-disciplinary membership. The meetings were chaired by a lead radiologist, and were also attended by the designated manager, the medical physics expert (MPE), a senior radiographer, the risk health and safety manager and the chief operating officer (COO). The COO was responsible for overseeing the day-to-day aspects of radiation protection in the radiology department, and had assumed this responsibility as a compliance action following the previous inspection.

The radiology department in Royal Victoria Eye and Ear Hospital consists of one general X-ray unit, a mobile X-ray unit and a cone-beam computed tomography (CBCT), which is not yet operational. The department provides medical exposures of ionising radiation to in-patients in the hospital and to out-patients, including those referred from the hospital's emergency department. The department is led by a senior radiographer who is supported by the COO, MPE, a team of radiologists and a number of radiography staff.

A sample of service user records for medical exposures were reviewed by the inspector and showed that appropriate persons as per the regulations were involved in referring and justifying medical exposures completed in the service. The inspector was also satisfied that only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service. The management team had developed a '*Radiation Protection Procedure*' which clearly outlined the allocated responsibilities for the radiation protection of service users.

The inspector noted 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.

Overall, the inspector was assured that service users were receiving a safe radiological service at Royal Victoria Eye and Ear Hospital.

Regulation 4: Referrers

The inspector reviewed a sample of medical exposure records and spoke with staff, and was satisfied that referrals for medical radiological procedures were only accepted from persons defined in Regulation 4.

The management team at Royal Victoria Eye and Ear Hospital had developed '*Radiation Safety Procedures*' which clearly outlined who could refer for medical radiological procedures in the service. This included medical practitioners, dentists and radiographers who were allocated responsibility to make adapted and secondary referrals. The inspector was also informed that plans were in progress to have an appropriately qualified nurse referrer in the service, whose scope for referrals would be limited to particular planar images approved by a local implementation group.

Judgment: Compliant

Regulation 5: Practitioners

From a review of documents and speaking with staff, the inspector was satisfied that only practitioners, as defined in Regulation 5, took clinical responsibility for individual medical exposures at Royal Victoria Eye and Ear Hospital.

Judgment: Compliant

Regulation 6: Undertaking

The inspector reviewed documentation including governance structure organograms and spoke with staff in relation to governance arrangements at Royal Victoria Eye and Ear Hospital. The RSC was a key part of the local governance structures for radiation protection in the hospital. The inspector was informed that the committee reported to the quality and safety executive committee, which in turn reported to the quality and safety sub-committee of the hospital council. The sub-committee meetings were chaired by an independent board member and reported to the council quarterly. The undertaking representative attended the RSC, chaired the quality and safety executive committee and also attended the quality and safety sub-committee of the hospital council meetings. These arrangements assured the inspector that there were good governance structures in place to inform the

undertaking of radiation protection issues in the radiology department.

However, the inspector noted that the management team had not completed a compliance plan action from the previous inspection, as radiation protection had not been added to the quality and safety executive committee meeting agenda. This meant that, although incidents involving medical exposures were discussed at other governance meetings, general radiation protection issues were not discussed outside of the RSC meetings. Therefore, the inspector was not satisfied that the undertaking's management team were meeting their responsibility for radiation safety in Royal Victoria Eye and Ear Hospital, as allocated in their '*Radiation Safety Procedure*'.

Throughout the day of the inspection, the inspector identified some issues under Regulations 8 and 14 which the undertaking's management team should address in order to ensure compliance with these regulations. This is further discussed in this report.

The inspector also noted that the following should be actioned to achieve compliance with Regulation 6 in Royal Victoria Eye and Ear Hospital :

- The undertaking's management team had developed a '*Policy and Procedure for Radiological Examination within the Radiology Department*' which clearly outlined the allocated roles and responsibilities for the justification of medical exposures. As part of the compliance plan following the previous inspection, the management team had committed to also updating the '*Radiation Protection Procedure*' with these roles and responsibilities, to ensure clarity for staff and the radiation protection of service users. While improvements in the documentation were evident, the inspector was not satisfied that it provided sufficient clarity for staff on their roles and responsibilities on justification of medical exposures.
- Overall, the inspector was satisfied that there were appropriate measures in place to provide adequate radiation protection to female service users who may be pregnant. However, the '*Radiation Protection Procedure*' required review to ensure that it clearly outlined the roles and responsibilities around inquiring on the pregnancy status of female service users.

Notwithstanding the above, the inspector was assured that there was a clear allocation of roles and responsibilities for the protection of service users in the facility, from medical exposure to ionising radiation, as required by Regulation 6(3).

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector observed that only persons entitled to act as a practitioner, as defined

in Regulation 5, carried out the practical aspects of and took clinical responsibility for the medical radiological procedures in Royal Victoria Eye and Ear Hospital.

It was also noted that practitioners and the MPE were involved in the optimisation process for medical exposures to ionising radiation.

From discussions with staff and a review of medical records, the inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From a review of documentation, the inspector saw that the undertaking's management team had engaged a MPE, from another facility, to provide the radiology department in the Royal Victoria Eye and Ear Hospital service with a MPE service. This included arrangements to ensure continuous access to the MPE's expertise.

The inspector also spoke with a number of staff who stated that this arrangement worked well and that they had continuous access to and support from the MPE.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and was satisfied that the involvement and contribution of the MPE in the facility met the requirements of this regulation. This review included the professional registration certificate of the MPE providing expertise in the facility.

The inspector noted that the MPE had been clearly allocated responsibilities, as specified in Regulation 20(2), across the radiological service. For example, they were involved in acceptance testing and the quality assurance (QA) of medical radiological equipment, and the inspector was informed that they had recently liaised with the senior radiographer in revising a QA programme for a piece of equipment. The MPE also reviewed and signed off local diagnostic reference levels (DRLs), and were available to provide advice and dose calculation for radiation incidents and attend the local RSC meetings.

The MPE was assigned the role of radiation protection advisor (RPA) at the facility, which satisfied the inspector that the MPE and the RPA liaised as appropriate.

Judgment: Compliant

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

From a review of documentation and discussions with relevant staff, the inspector was satisfied that the level of MPE involvement in medical radiological practices was commensurate with the radiological risk posed by the facility.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, the inspector noted that the undertaking's management team had implemented many of the compliance actions from the previous inspection, and was committed to improving the radiation protection of service users. For example, by the use and refinement of diagnostic reference levels (DRLs).

All referrals reviewed by the inspector during the 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. The justification of medical exposures in advance, by a practitioner, was evident for medical radiological procedures reviewed by the inspector. However, the inspector was informed that administrative staff were tasked with seeking to obtain previous diagnostic information or medical records relevant to planned exposures, which was not in line with the local '*Radiation Protection Procedure*' or in compliance with Regulation 8 (12).

The inspector followed up on a compliance plan action from the previous inspection and saw that the management team had established and reviewed local DRLs for medical radiological examinations that were frequently completed in the service. From discussions with staff the inspector was satisfied that they were used for all medical radiological procedures conducted in the service.

From a review of documentation, the inspector was satisfied that there was an established QA programme for radiological equipment in the service, and that the programme was discussed at local RSC meetings. However, the inspector was not assured that the management team had good oversight that this programme was performed as scheduled. This is further discussed under Regulation 14 Equipment below.

The inspector reviewed the process in place to determine the pregnancy status of service users, where relevant and was assured that this process was safe and

effective. The inspector also reviewed documentation that evidenced that there were good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation.

Overall, the inspector was 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

From a review of a sample of medical records, the inspector was satisfied that referrals for medical exposures were in writing and stated the reason for the request and were accompanied by sufficient medical data to enable the practitioner to adequately consider the benefits and risks of the medical exposure. This review also showed that the recording of justification in advance had been completed by practitioners and referrers.

Information about the benefits and risks associated with the radiation dose from medical exposures was available to service users by means of information leaflets and posters in the waiting area of the facility. The inspector noted that the management team had made good efforts to ensure that this information was presented in a way that could be easily understood by service users.

In line with Regulation 8, practitioners and referrers in Royal Victoria Eye and Ear Hospital had been allocated responsibility to obtain previous diagnostic information or medical records relevant to planned exposures. However, during discussions with staff, the inspector was informed that administrative staff were completing the task of seeking the previous diagnostic information or medical records relevant to planned exposures. The inspector was also informed that there no control system in place for practitioners to indicate that they were assured that efforts had been made to seek to obtain previous diagnostic information or medical records. This system of administrative staff obtaining previous diagnostic information or medical records is not in compliance with Regulation 8 (12) and was not in line with the management team's '*Radiation Protection Procedure*' which states that it is the responsibility of the radiographer or radiologist to obtain such information.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

From a review of documentation, the inspector was satisfied that DRLs for frequently completed radiological examinations had been established, and where possible compared to national levels.

Following equipment upgrade in the facility, the inspector observed that, among

others, the DRLs for two particular examination types had been established, reviewed and discussed at a RSC meeting. Although, national DRLs were not available to compare for two examination types, a multi-disciplinary team had agreed to further review the DRL data in an attempt to further lower exposures to service users. During the course of the inspection, the inspector was informed that the additional review had been completed, and also observed guidance posters displayed in clinical areas which demonstrated that corrective actions had been implemented following the review. This system of DRL review and attention to radiation protection for service users was identified as an area of good practice within the facility.

Judgment: Compliant

Regulation 14: Equipment

The inspector was provided with an up-to-date inventory of medical radiological equipment in the service, and reviewed records which showed that acceptance testing for all radiological equipment had been completed before the first clinical use.

From discussions with staff and a review of the procedure '*Equipment Management and Quality Control Plan within the Radiology Department*', the inspector was informed that the quality assurance programme for equipment had been revised and updated since the previous inspection in November 2022. The programme comprised of routine performance testing by radiographers and annual testing by the MPE.

The inspector reviewed documentation and saw that the annual testing had been completed as scheduled. However, a review of routine testing records showed that on three separate dates, when service user examinations had been performed, routine testing was not performed. Although the records showed that there no issues with the equipment's performance on days that routine testing had been performed, the inspector was not satisfied due to the gaps in testing, that the undertaking had good arrangements in place to ensure that all medical radiological equipment in use in the service was kept under strict surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Overall, the inspector was assured that appropriate measures were in place to minimise the risks, associated with potential fetal irradiation, during medical

exposures of female patients of childbearing age in the Royal Victoria Eye and Ear Hospital. The local '*Radiation Protection Procedures*' stated that practitioners were responsible for inquiring on and recording in writing the service user's pregnancy status, where relevant, and from discussions with practitioners, the inspector was satisfied that they were aware of their specific responsibilities in this area.

The inspector also observed that, in line with a compliance plan action from the previous inspection, the management team had placed notices to raise awareness of the special protection required during pregnancy in advance of medical exposures, in service user waiting areas.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The undertaking's management team had a process in place for the recording and review of any incidents and near misses, involving accidental or unintended exposures to ionising radiation. The inspector spoke with a number of staff who clearly described this process, and also demonstrated how they accessed and used the local incident reporting system.

From a review of documentation and discussions with the management team, inspectors noted that if an incident were to occur it would be discussed at both the RSC and the Quality and Patient Safety Executive meetings. These meetings were attended by the Designated Manager of the Royal Victoria Eye and Ear Hospital, who was also the undertaking representative.

The inspector also followed up on a compliance plan action from the previous inspection, and saw that the hospital's policies on the local incident management process had been updated and were now aligned. This ensured that if an incident or near miss were to occur, they would be appropriately managed and in turn promoted the radiation protection of all service users.

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	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	Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

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

Inspection ID: MON-0038478

Date of inspection: 13/09/2023

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Radiation protection was added as an agenda item to the Quality and Safety Executive Committee meeting agenda on 19/10/2023. The senior radiographer/ RPO was invited to attend the meeting on 19/10/2023 to provide an update on radiation safety and the HIQA inspection.</p> <p>The roles and responsibilities of the referrers and practitioners with regards to justification and enquiring about pregnancy status of relevant females have been updated in the radiation safety procedures. Revised radiation safety procedures will be signed off at the next Radiation Safety Committee Meeting on 6th December 2023.</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>The radiographers now have access to patient's previous diagnostic information and review patient's imaging history themselves. PPGC-RAD-05 'Policy and Procedure for Radiological Examination within the Radiology department' has been revised to reflect this change in practice. This was implemented on 14/10/2023. Revised procedure will be signed off at Radiation Safety Committee meeting on 6th December 2023.</p>	

Regulation 14: Equipment	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: A KPI is being introduced to monitor compliance with performance of routine QC, daily, weekly and monthly. The results of the KPI will be reported monthly to the COO and 6 monthly to the RSC. A template has been set up to record the results.</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	06/12/2023
Regulation 8(12)	The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records	Substantially Compliant	Yellow	14/10/2023

	relevant to a planned exposure and consider these data to avoid unnecessary exposure.			
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	01/11/2023