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:	Incorporated Orthopaedic Hospital of Ireland
Undertaking Name:	Incorporated Orthopaedic Hospital of Ireland
Address of Ionising Radiation Installation:	Castle Ave, Clontarf, Dublin 3
Type of inspection:	Announced
Date of inspection:	23 March 2023
Medical Radiological Installation Service ID:	OSV-0006142
Fieldwork ID:	MON-0039307

About the medical radiological installation:

The Incorporated Orthopaedic Hospital of Ireland is a voluntary hospital (Section 38) operating in Community Health Care Organisation 9. It is a 160 bed post-acute rehabilitation facility, with a staff complement of 271. The Incorporated Orthopaedic Hospital of Ireland provides consultant-led older peoples, neuro-speciality and amputee rehabilitation services, and post-operative orthopaedic rehabilitation services with other local hospitals.

The Incorporated Orthopaedic Hospital of Ireland's X-ray department is a one unit general radiography room, with a digital radiography system. It provides radiology services to in-patients, and also to out-patients via community general practitioners referrals. The X-ray department is open Monday to Friday, and does not provide an after-hours or weekend service.

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
Thursday 23 March 2023	10:00hrs to 14:30hrs	Kirsten O'Brien	Lead
Thursday 23 March 2023	10:00hrs to 14:30hrs	Margaret Keaveney	Support

Governance and management arrangements for medical exposures

The undertaking the Incorporated Orthopaedic Hospital of Ireland is located on the campus of the Incorporated Orthopaedic Hospital of Ireland, and is responsible for ensuring that the radiological services within the hospital meet the regulatory requirements. The radiology department consists of a single X-ray unit that provides medical exposures of ionising radiation to both out-patients referred by general practitioners and local hospitals, and to in-patients referred by in-house medical officers.

Inspectors were assured that the undertaking had appropriate governance and management arrangements in place to ensure good oversight of the radiation protection of service users. However, on the day of the inspection, inspectors discussed the terms of reference of the Radiation Safety Committee (RSC) with the management team and established that minor updates to the document were required to ensure that it accurately reflected the reporting structures for the RSC. Inspectors also noted that the undertaking's Pregnancy Policy required updating to ensure that it clearly reflected local practices and was aligned with the regulations. This is further discussed below under Regulation 16: Special protection during pregnancy and breastfeeding.

Inspectors were assured that there were systems and processes in place to ensure that only persons recognised by the regulations were entitled to refer an individual for medical radiological procedures. On the day of inspection, inspectors reviewed a sample of patient records which evidenced that medical exposures took place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and the Medical Physics Expert (MPE) were found to be involved in the optimisation process for medical exposure to ionising radiation. There was also satisfactory evidence that referrers and practitioners were involved in the justification process for individual medical exposures.

From discussions with staff and documentation viewed, inspectors were satisfied that the undertaking had suitable arrangements in place to ensure there was appropriate involvement and contribution of a MPE as required by the regulations.

Regulation 4: Referrers

Inspectors were satisfied that the undertaking met the requirements of this regulation. From discussions with staff and records viewed by inspectors, referrers were clearly identifiable in each of the referrals reviewed and professional registration numbers could be checked and verified by staff if needed.

Judgment: Compliant

Regulation 5: Practitioners

On the day of inspection, five patient records and other documentation were reviewed. Inspectors also spoke to staff and management in the service. From these reviews and discussions, inspectors were assured that only persons entitled to act as a practitioner, as defined by the regulations, take clinical responsibility for medical exposures in the service.

Judgment: Compliant

Regulation 6: Undertaking

A clear allocation of responsibilities to ensure safe and effective care for those undergoing exposure to ionising radiation was outlined in documentation reviewed by inspectors. Inspectors also spoke to numerous staff in the service who were aware of their own and collective responsibilities in ensuring the safe delivery of medical exposures to patients.

The governance arrangements demonstrated that the Chief Executive Officer (CEO) was the chairperson of the Executive Management Team (EMT). The EMT reported to the Quality, Safety and Risk Management Committee, which was a sub-committee of the Board of Governors. Inspectors noted that the RSC also reported to the EMT. This reporting pathway provided the CEO with oversight of any radiation protection issues or concerns, and assured inspectors that the undertaking's EMT and Board of Governors had robust oversight of the ionising radiation service in the Incorporated Orthopaedic Hospital of Ireland. Inspectors also reviewed the Board's meeting minutes which demonstrated that the X-ray department was discussed at Board level. The CEO was both the undertaking representative and designated manager of the radiological services in the Incorporated Orthopaedic Hospital of Ireland.

Inspectors also reviewed the minutes of the previous three RSC meetings, which were chaired by a consultant radiologist and attended by radiography staff, the Quality Improvement Officer, the Risk Officer and the MPE. Standing items on the agenda included radiation safety, training and education, quality assurance, incidents, and clinical audit. Inspectors also noted that the replacement of the X-ray unit was also discussed and planned for at these quarterly meetings.

Inspectors also saw evidence that the undertaking supported the continual improvement of the service through quality assurance activities. For example, there was an annual auditing schedule in place for various clinical aspects of the service, and equipment services were also scheduled well in advance to ensure that they were serviced as advised by manufacturer's guidelines. Records showed that

training in radiation protection was also completed by all staff, involved in the care of patients receiving a medical exposure of ionising radiation.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were assured that all medical exposures were performed under the clinical responsibility of a practitioner as defined by the regulations, and that these practitioners were clearly identifiable.

It was also clear from discussions with staff and a review of documents that referrers, practitioners and the MPE were aware of their responsibilities in the optimisation of doses delivered to service users during medical exposures.

Inspectors spoke with the radiologist consultant who outlined their referral role and responsibilities, which included involvement in justification through the referral process, and clinical evaluation of the procedure outcome.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The undertaking had arrangements in place to ensure access to and continuity of MPE services, and therefore met the requirements of this regulation.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the MPE was involved in all aspects of medical exposures, such as the quality assurance of medical radiological equipment, dosimetry and optimisation, including establishing and reviewing diagnostic reference levels (DRLs). The MPE had also been assigned the role of Radiation Protection Advisor in the service.

A review of the RSC meeting minutes revealed that the MPE attended these meetings, and contributed to discussions such as quality assurance of the service and equipment replacement programmes. Inspectors were also assured that the MPE was informed of any significant events involving medical exposures to ionising radiation that occurred in the service, and that they provided radiation protection

training for staff.

Judgment: Compliant

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

Inspectors were assured that there was appropriate involvement of the MPE involvement in medical radiological practices, and that the level of involvement was commensurate with the radiological risk posed by the services provided to service users. In addition, staff verified that the MPE was readily available for consultation on matters relating to radiation protection of service users.

Judgment: Compliant

Safe Delivery of Medical Exposures

From documentation reviewed and discussions with staff, inspectors were satisfied that the undertaking was committed to improving the radiation protection of service users by ensuring that medical radiological procedure doses were kept as low as reasonably achievable, through the use and regular review of diagnostic reference levels (DRLs), and the implementation of a robust quality assurance programme on all aspects of the service. However, action was required to update the service's pregnancy policies.

All referrals reviewed by inspectors 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 all medical radiological procedures reviewed by inspectors over the course of the inspection.

Inspectors were assured that the undertaking had established, regularly reviewed and used diagnostic reference levels (DRLs) as required by the regulation. Inspectors reviewed the undertaking's policy and procedure on the *Establishment and Use of Diagnostic Reference Levels* which clearly detailed the process to be followed when a medical radiological exam had exceeded the local DRL.

From the review of records and speaking with staff on the day of inspection, inspectors were assured that the undertaking had implemented and maintained a quality assurance programme to ensure that the equipment was safe for use and fit for purpose. Inspectors also noted that equipment and quality assurance programmes were routinely discussed at the radiation safety committee meetings.

On the day of inspection, inspectors observed a number of notices, in a variety of languages, had been placed in patient changing rooms and waiting areas, to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. As the practitioners, radiographers were assigned the responsibility for inquiring on patients' pregnancy status, where relevant, in line with the regulations. Inspectors reviewed a sample of referrals and found that, where relevant, practitioners had inquired on and recorded in writing the pregnancy status of patients. However, a review of the two local pregnancy policies showed that they required review as they did not accurately align with each other or with the regulations. This is further discussed under Regulation 16: Special protection during pregnancy and breastfeeding, below.

Inspectors saw documented evidence that the undertaking had adequate arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. These arrangements included ensuring that the Authority was notified of any significant events. Inspectors also found evidence that staff had proactively identified measures to mitigate any potential accidental and unintentional exposures in the service.

Overall, inspectors were satisfied that the Incorporated Orthopaedic Hospital of Ireland had effective systems and processes in place to ensure that service users, undergoing medical exposures of ionising radiation, received a safe service.

Regulation 8: Justification of medical exposures

The sample of referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data to allow practitioners to consider the benefits and the risk of the medical exposure. Inspectors also spoke with practitioners who detailed the local process of justifying medical exposures in advance of them being conducted.

There was evidence in records that the justification process, including review of medical information and previous diagnostic procedures, had taken place in advance of the medical exposure being conducted, and this justification was documented for all records of individual medical exposures viewed by inspectors.

Information about the benefits and risks associated with the radiation dose from medical exposures was observed in the form of posters in the waiting areas and changing rooms at the X-ray department.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were assured that DRLs for radiological examinations were established and regularly reviewed by appropriate personnel, to ensure that they were comparable to national diagnostic reference levels. Inspectors observed that local DRLs were displayed prominently in the console area of the X-ray unit, for easy reference by the practitioners.

There was also evidence that DRLs were regularly reviewed to ensure that they contributed to the optimisation of doses for the protection and safety of patients. Inspectors noted that the undertaking's policy on the *Establishment and Use of Diagnostic Reference Levels* stated that a full general DRL audit must be completed following any changes in imaging equipment, and inspectors noted that this had been completed by the undertaking following the replacement of equipment in October 2021.

Judgment: Compliant

Regulation 14: Equipment

Inspectors viewed evidence that the undertaking had adequate arrangements in place to ensure that all medical radiological equipment in use in the service was kept under strict surveillance regarding radiation protection. A review of documentation showed that an appropriate quality assurance programme for the equipment had been established and was implemented. This quality assurance programme included annual MPE testing, regular performance testing by radiographers and the prospective scheduling of preventative maintenance and servicing of the X-ray equipment. Inspectors also found evidence that systems were in place to ensure that any performance issues with the medical radiological equipment were actioned.

Inspectors also saw that the replacement of the equipment had been discussed at recent RSC meetings and at monthly EMT meetings, and that the risk of disruption to the radiology service, should the equipment fail, had been placed on the corporate risk register, with an appropriate risk owner and risk measures in place.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were assured that there was an established and safe process in place to determine the pregnancy status of service users, where relevant.

However, inspectors reviewed the undertaking's *Policy on Pregnancy with Respect to Patients in the Child Bearing Years (12-55yrs)* and *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures*, and saw that the documented process of establishing the pregnancy status of a service user did not align between the documents. In particular, the personnel named as responsible for enquiring into pregnancy status of service users differed in the documents.

Also, the definition of who was entitled to act as a practitioner for the purposes of establishing pregnancy status in the *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* did not include the radiographer, which differed from the Radiation Safety Procedures and day-to-day practice.

A review of other definitions in the policies was also required to ensure that they aligned with the current regulations.

Notwithstanding these document updates, inspectors were assured that day-to-day practices in determining the pregnancy status of service users were safe and effective.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Although no significant events had been recorded, a review of the incident management policy and records of incidents and near misses, involving or potentially involving accidental or unintended exposures to ionising radiation, demonstrated to inspectors that the undertaking had implemented an appropriate system for recording such events. Inspectors were assured that the undertaking had adequate oversight of any accidental or unintended exposures, and significant events, as they were a standing item on the agenda of the radiation safety committee.

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	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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Incorporated Orthopaedic Hospital of Ireland OSV-0006142

Inspection ID: MON-0039307

Date of inspection: 23/03/2023

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 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding: Review current pregnancy and breastfeeding policy in the Local Rules, specifically to the areas that were deemed not fully compliant and need to be updated and aligned. This policy update is currently being reviewed and updated with a set completion date of 31 May 2023.	

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 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	31/05/2023