



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Northbrook Clinic
Undertaking Name:	Dr John A Lordan
Address of Ionising Radiation Installation:	15A Northbrook Road, Ranelagh, Dublin 6
Type of inspection:	Announced
Date of inspection:	16 June 2021
Medical Radiological Installation Service ID:	OSV-0006931
Fieldwork ID:	MON-0028249

About the medical radiological installation:

Dr John A Lordan operates at the Northbrook Clinic as a specialist endodontic referral practice. Patients are referred for surgical and non-surgical endodontic treatment.

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 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 doing, we describe the overall effectiveness of an undertaking in ensuring the quality and safe conduct of medical exposures. It examines how the undertaking provides the technical systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential

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.

risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure.

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 16 June 2021	13:00hrs to 14:30hrs	Lee O'Hora	Lead

Summary of findings

An on-site inspection of the undertaking John A. Lordan operating at Northbrook Clinic was completed on 16 June 2021.

The inspector found effective management arrangements at Northbrook Clinic with a clear allocation of responsibility for the protection of service users undergoing dental radiological exposures. Reporting structures and key personnel were well defined in documentation reviewed and clearly articulated to the inspector on the day of inspection.

The inspector was assured that processes were in place to ensure the safe conduct of dental radiological procedures by the undertaking. The inspector was satisfied that the specialist dentist operating at the practice acted as the referrer and the practitioner, and took clinical responsibility for all dental radiological procedures.

The inspector was confident that the undertaking ensured that diagnostic reference levels (DRLs) were established, reviewed and used. However, on the day of inspection, written protocols for every type of standard dental radiological procedure were not available and information relating to patient exposure did not form part of the report of dental radiological procedures. These non-compliances were acknowledged by the undertaking as areas for potential improvement to ensure regulatory compliance in the future.

The inspector was assured that all dental radiological equipment was kept under strict surveillance regarding radiation protection. Medical physics expert (MPE) professional registration, continuity of expertise and involvement was well documented and articulated to the inspector by staff and satisfied regulatory requirements. However, it was noted that clinical audits suggested by the MPE had not yet been implemented - this is seen as an area for improvement as the inclusion of routine clinical audit would be considered a quality improvement tool with the potential to improve service user outcomes.

Overall, while the instances of non-compliance found on inspection are an area for improvement, the inspector found that the undertaking demonstrated good levels of compliance with the other regulations considered on the day of inspection.

Regulation 4: Referrers

Following review of documentation and speaking with staff, the inspector was satisfied that all referrals for dental radiological procedures originated within the practice from the registered dentist. Up-to-date professional registration information

was supplied to the inspector and satisfied relevant regulatory requirements.

Judgment: Compliant

Regulation 5: Practitioners

The inspector reviewed the professional registration details of the practitioner operating at the Northbrook Clinic. All professional registration information was up to date and satisfied relevant regulatory requirements of Regulation 5.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspector outlined a clear allocation of responsibility for the protection of service users by John A. Lordan operating at the Northbrook Clinic. The relevant responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspector during the course of the inspection.

Judgment: Compliant

Regulation 8: Justification of medical exposures

The inspector was informed that the dentist operating at the practice was both the referrer and practitioner for all dental radiological procedures carried out on site. This was confirmed by reviewing a sample of patient records which also assured the inspector that all dental exposures were justified in advance. Furthermore, the referral records reviewed on the day stated the reason for the dental X-ray as well as providing sufficient medical data for the procedure.

Staff spoken to on the day demonstrated clearly their ability to communicate the benefits and risks of dental X-ray procedures to patients.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied following review of documentation and speaking with staff that all dental exposures took place under the clinical responsibility of the dentist operating at the practice and the MPE was involved in the optimisation process with the dentist.

The inspector was informed that practical aspects of dental radiological procedures were not delegated to other individuals at the time of inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Records of MPE performance testing supplied to the inspector as part of the inspection process detailed that diagnostic reference levels (DRLs) were established, regularly reviewed and used.

Judgment: Compliant

Regulation 13: Procedures

Staff articulated good knowledge of exposure parameters used when imaging and exposure factors were pre programmed into the dental radiological equipment, but written protocols for every type of standard dental radiological procedure were not available on the day of inspection.

The inspector reviewed patient reports and was subsequently informed by staff that information relating to the patient exposure did not routinely form part of the report.

It was noted in the MPE performance testing records from 14 February 2020, that clinical audit should be completed, kept on record and be available for inspection. No records of clinical audit were available on the day of inspection.

Judgment: Not Compliant

Regulation 14: Equipment

The inspector was satisfied that all dental radiological equipment was kept under strict surveillance. Records of MPE commissioning testing and performance testing were reviewed by the inspector and satisfied regulatory requirements.

A full radiological equipment inventory was supplied in advance of the inspection

and this was verified on site by the inspector.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspector was assured that the necessary arrangements were in place to ensure continuity of expertise of the MPE for the undertaking John A. Lordan operating at the Northbrook Clinic.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Up-to-date MPE registration details were supplied to the inspector. The inspector was satisfied that the responsibilities, advice and contributions of the MPE satisfied regulatory requirements of Regulation 20.

Judgment: Compliant

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

Following document review and speaking with staff, the inspector was satisfied that the involvement of the MPE was appropriate for the service provided by John A. Lordan.

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
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	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

Compliance Plan for Northbrook Clinic OSV-0006931

Inspection ID: MON-0028249

Date of inspection: 16/06/2021

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 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: In response to compliance regulation 13(1)13(2) as per report. We are a practice limited to endodontics and our patients are subject to periapical radiographs exposure for diagnosis, treatment and completion of root canal treatments. Our protocols are very precise and exposure to patients are almost 50% less than the national average as measured by our MPE. Going forward we have initiated a record of exposure parameters for each patient and this is recorded on patient clinical information commenced on 20/06/2021.</p> <p>Imaging protocols will be formulated and in place by 30th September 2021 to include to minimal number of radiographs views for each procedure, radiographic technique approach, exposure factors and positioning techniques for each procedure. Due to the specialist nature of our practice and limited range of treatment options provided, the protocols will be very similar for each patient.</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 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.	Not Compliant	Orange	30/09/2021
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	20/06/2021