



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:	Northbrook Healthcare Services Limited
Address of Ionising Radiation Installation:	15a Northbrook Rd, Ranelagh, Dublin 6
Type of inspection:	Announced
Date of inspection:	11 November 2020
Medical Radiological Installation Service ID:	OSV-0006220
Fieldwork ID:	MON-0030760

About the medical radiological installation:

Northbrook Healthcare Services Limited at Northbrook Clinic is a dental imaging referral centre supplying lateral cephalometry, orthopantomography and cone beam computed tomography for registered dental practitioners. Lateral cephalometric radiographs are used to provide an image of the side of the face, orthopantomograms provide panoramic views of the jaw and teeth and cone beam computer tomography (CBCT) is used to obtain multiple images from different angles to create a 3-Dimensional image of a single tooth or the entire jaw.

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 11 November 2020	12:00hrs to 14:00hrs	Lee O'Hora	Lead

Summary of findings

The inspector found effective management arrangements at Northbrook Healthcare Services Limited with a clear allocation of responsibility for the protection of service users undergoing dental 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 Northbrook Healthcare Services Limited has processes in place to ensure that all dental procedure referrals are accompanied by the relevant information and justified in advance by a practitioner. Information on the risks associated with exposure to ionising radiation was well articulated by staff in the clinical area to the inspector. However, two areas for potential improvement in the justification of individual medical exposures were noted to include the documentation of practitioner justification in the referral record and the availability of risk benefit information for service users.

The inspector was satisfied that Northbrook Healthcare Services Limited ensured all dental exposures took place under the clinical responsibility of a practitioner and that the justification and optimisation process involved the appropriately qualified individuals. The practical aspects of dental procedures were delegated to an appropriate individual at the time of inspection and this was recorded in the local radiation safety procedures. All radiation safety training of staff involved in dental exposures was evidenced and records of ongoing radiation safety training for persons delegated the practical aspects of dental exposures as well as the practitioner were reviewed by the inspector. Overall, Northbrook Healthcare Services Limited demonstrated a clear commitment to the ongoing radiation safety training of staff involved in the exposure of service users to ionising radiation.

The inspector saw evidence of diagnostic reference levels (DRLs) being established, reviewed and used. Staff demonstrated an excellent knowledge of local facility DRLs for each procedure performed at Northbrook Healthcare Services Limited. Records of DRL reviews completed in October were available but records of corrective actions to address a local facility DRL exceeding the national value was not completed at the time of inspection and must be addressed to ensure full compliance with Regulation 11.

The inspector reviewed extensive manufacturer service records as well as medical physics expert (MPE) quality assurance reports which clearly demonstrated Northbrook Healthcare Services Limited's commitment to keeping dental radiological equipment under strict surveillance. MPE professional registration, continuity of expertise and involvement was well documented. All MPE optimisation recommendations noted in quality assurance reports carried out on 21 October 2020 had been addressed or implemented at the time of inspection which demonstrated the timely execution of MPE advice by Northbrook Healthcare Services Limited.

Staff articulated detailed knowledge of exposure factors and displayed extensive knowledge of imaging technique to the inspector. Examples of general information relating to imaging technique was documented locally but written protocols for every type of standard dental radiological procedure were not available at the time of inspection. Similarly, staff demonstrated good knowledge of rationale for imaging but evidence of availability of referral guidelines for dental imaging was not found on inspection, these were identified as areas for improvement with management at Northbrook Healthcare Services Limited but were not considered to have associated service user safety concerns.

Overall, while there were some areas requiring improvement and should be addressed in order to demonstrate full compliance with the regulations, there were many areas of good practice noted on inspection to ensure patient safety during dental exposure to ionising radiation.

Regulation 4: Referrers

Documentation reviewed by the inspector outlined that referrals for imaging by Northbrook Healthcare Services Limited are accepted from dental practitioners only. The inspector reviewed a sample of referrals on site, all of which, had referring dental practitioner name and signature.

Judgment: Compliant

Regulation 5: Practitioners

One dental practitioner operates at Northbrook Healthcare Services Limited at Northbrook Clinic. Documentation of associated professional registration was reviewed and up to date.

Judgment: Compliant

Regulation 6: Undertaking

A clear allocation of responsibility was articulated to the inspector on the day of inspection. Northbrook Healthcare Services Limited at Northbrook Clinic delivers imaging services with an on site practitioner who is also the undertaking representative and designated manager. Responsibility for practical aspects of dental imaging is also delegated to a single dental nurse operating on site.

Judgment: Compliant

Regulation 8: Justification of medical exposures

Documentation reviewed demonstrated that Northbrook Healthcare Services Limited required referral information which met all regulatory requirements for all referrals. Sample referrals reviewed on site were in writing, stated the reason for requesting the particular procedure and were accompanied by sufficient medical data. The inspector was informed that all referrals were reviewed and justified in advance by the practitioner but a system to record practitioner justification was not in place at the time of inspection, this should be addressed to ensure complete compliance with all aspects of Regulation 8.

Staff met with on inspection articulated in depth knowledge of the routine patient doses associated with all dental radiological procedures and were able to communicate the associated risks in a manner easily understood by service users. However, there was an absence of information relating to the risks and benefits of dental exposures available for service users at the time of inspection and this should be updated to evidence full compliance.

Judgment: Substantially Compliant

Regulation 9: Optimisation

The Inspector reviewed MPE quality assurance testing records, dated the 21 October 2020, which suggest a number of actions. At the time of inspection all actions had been implemented which demonstrated the undertakings commitment to help ensure that all doses due to medical exposure are kept as low as reasonably achievable.

Judgment: Compliant

Regulation 10: Responsibilities

The inspector was satisfied that Northbrook Healthcare Services Limited at Northbrook Clinic ensured that all dental exposures take place under the clinical responsibility of the practitioner.

Northbrook Healthcare Services Limited supplied dental referrers with the patient imaging for all referrals. Documentation reviewed by the inspector stated that Northbrook Healthcare Services Limited were assured that the referring dental

practitioner had sufficient training in cone beam computed tomography (CBCT) to interpret the CBCT images provided by Northbrook Healthcare Services Limited. The inspector was informed that Northbrook Healthcare Services Limited supplies training in manipulation and interpretation of CBCT imaging to referrers when needed. The inspector was also informed that information on further resources to assist in the manipulation and interpretation of CBCT images was supplied to referrers. Practitioner training records specific to CBCT were reviewed and the inspector was assured that the practitioner has undertaken appropriate training in CBCT and, at the time of inspection, was undergoing further training in CBCT.

Evidence that practitioner, MPE and those that conduct X-rays persons were involved in the optimisation process was supplied to the inspector. The justification process was documented and clearly articulated to the inspector during the inspection. The inspector was satisfied that the justification process involved the referrer and practitioner.

The practical aspects of dental radiological procedures were delegated by the undertaking to an appropriately registered dental nurse. Evidence of this delegation was recorded in documentation reviewed by the inspector. Professional registration, radiation safety training and ongoing annual training records of the person delegated practical aspects of dental radiological procedures were reviewed by the inspector during the inspection process.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

The inspector was satisfied that DRLs had been established reviewed and used. DRLs were available in the clinical area in a radiation safety folder. Staff articulated detailed knowledge of procedure DRL values for all procedures done. The inspector was assured that staff had access to and routinely used local facility DRL data clinically.

MPE quality assurance documentation completed on the 21 October 2020 highlighted that the local facility DRL value for the orthopantomogram (OPG) dental procedure was above that of the national DRL. The inspector was informed that corrective actions for this particular exposure type were currently under consideration but had not been completed and this was highlighted as an area for improvement.

Judgment: Substantially Compliant

Regulation 13: Procedures

Staff articulated detailed knowledge of exposure factors and demonstrated extensive knowledge of imaging technique to the inspector. Some general information relating to imaging technique was documented locally but written protocols for every type of standard dental radiological procedure were not available in the clinical area at the time of inspection.

Staff demonstrated good knowledge of rationale for imaging but evidence of availability of referral guidelines for dental imaging was not found on inspection.

Inspectors reviewed records of image quality audits. Audits reviewed reported high image quality scores across all imaging procedures at Northbrook Healthcare Service Limited.

Judgment: Substantially Compliant

Regulation 14: Equipment

Extensive manufacturer service reports, as well as MPE quality assurance reports, were reviewed by the inspector. The inspector was satisfied that all radiological equipment was kept under strict surveillance.

An equipment inventory was supplied and verified on site.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Local documentation reviewed by the inspector clearly outlined the process for management of accidental and unintended exposures and significant events. Staff articulated the radiation incident management process to the inspector during the course of the inspection. At the time of inspection no incidents or near misses had been recorded at Northbrook Healthcare Services Limited at Northbrook Clinic. However, the inspector was satisfied that this was due to the nature of the patient pathway and there were no concerns in relation to an absence of reporting.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Medical Physics Expert (MPE) professional registration was reviewed on site by the inspector and up to date. The inspector was satisfied that the necessary arrangements were in place to ensure continuity of expertise of the MPE by Northbrook Healthcare Services Limited.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Evidence of MPE involvement in quality assurance, patient dose optimisation, image quality audit and establishment and review of diagnostic reference levels was reviewed by the inspector.

Judgment: Compliant

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

After document review and following feedback from staff, the inspector was satisfied that the involvement of the MPE at Northbrook Healthcare Services Limited at Northbrook Clinic was appropriate and commensurate with the risk at the practice.

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	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	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-0006220

Inspection ID: MON-0030760

Date of inspection: 11/11/2020

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 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: We have formulated a new referral letter protocol which referring practitioners will send to Northbrook on their headed paper and signed by practitioner which states 1) the clinical reason for requesting the x-ray, 2) the type of x-ray, 3) any relevant information we may require prior to taking the requested x-ray.</p> <p>On receipt of a referral letter for x-ray, it will be looked at and if sufficient justification is provided, we will stamp it and sign as justified before taking the x-ray. This stamped signed record will then be filed and kept on our records.</p> <p>This will be achieved by the 28 -02- 2021.</p> <p>We have already printed and available to patients and referring practitioners, the Dap for all forms of x-rays performed at Northbrook Clinic. This form includes Dap for Opg, Lateral skull, all volumes of CBCT at variable Voxel sizes. Also included are the average background radiation per day, radiation levels on flight from Dublin to London and Dublin to New York for patients and referrers to be able to make informed judgement on risks involved Vs the benefit of having the x-ray. This information is available in the x-ray room in printed form.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: We have, over the past month, reduced the Kv and Ma to achieve below national DRLs for Opg x-rays from 120 to 80 Dap. The image quality is still excellent, and we will get the Planmeca engineer to attend early in 2021 to reset the</p>	

default values on our x-ray machine to reflect this lower value Dap. All other settings for small and large Patient's Dap values will be lowered accordingly.
This will be achieved by 28/2/2021

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: We will have in place written protocols for all types of x-rays we take in the x-ray room. This will include Protocols for patient positioning, Kv, Ma, selection of appropriate size and age group, to optimise outcomes for patients.

This will include instructions for CBCT to include volume size, volume area, Voxel size to reflect the ALARA principle, while still obtaining an image quality compatible with the clinical requirements for the image. This information will also be made available to referring dentists.

All regulations for referral for x-rays are adapted within the facility and are available for all referrers on request. We will send copies of referral criteria and appropriate regulations to referral dentists and also make available to them clarification of requirements for referral if asked to do so.

This will be achieved by 28-02- 2021

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 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	28-02-2021
Regulation 8(15)	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.	Substantially Compliant	Yellow	28-02-2021

Regulation 11(7)	An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.	Not Compliant	Orange	28-02-2021
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	28-02-2021
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.	Not Compliant	Orange	28-02-2021