



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	The James Clinic, Enfield
Undertaking Name:	The James Clinic
Address of Ionising Radiation Installation:	Enfield Court, Main Street, Johnstown, Enfield, Meath
Type of inspection:	Announced
Date of inspection:	17 August 2021
Medical Radiological Installation Service ID:	OSV-0007993
Fieldwork ID:	MON-0033758

About the medical radiological installation:

The James Clinic, is a ten-surgery dental clinic located in Enfield, Co. Meath. Three of the dental surgeries are used by dental hygienists and seven surgeries are used by dentists providing general dental treatment, orthodontic treatment, and implant and periodontal treatment. A portable handheld x-ray machine used to take periapical exposures and bite-wing dental x-rays and is used for general dental treatments. There is a dedicated x-ray room with an integrated scanner and cephalometric scanner. This scanner is used to obtain: Orthopantomograms, Cone Beam Computed Tomography, (CBCT), 3D x-rays and Cephalometric Radiographs. This scanner provides two and three dimensional images and is used in the planning of complex dental treatments, which include Orthodontic treatment, implants, wisdom teeth removal and full mouth rehabilitation.

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
Tuesday 17 August 2021	09:40hrs to 11:40hrs	Noelle Neville	Lead
Tuesday 17 August 2021	09:40hrs to 11:40hrs	Kay Sugrue	Support

Summary of findings

An inspection of The James Clinic, Enfield was conducted by inspectors on 17 August 2021 following receipt of information that medical exposures to ionising radiation were being conducted for a considerable period of time without notifying HIQA as required by Regulation 6(2). Upon receipt of this information, inspectors initially wrote to The James Clinic to confirm medical exposures were being conducted and this was confirmed in writing. Subsequently, a declaration of undertaking (NF200) form was submitted to address this oversight. It was also determined on the day of inspection that the undertaking had failed to declare that it was conducting Computed Tomography (CT) exposures and this was as a result of an administrative oversight and was corrected immediately following the inspection.

During the inspection, management described the allocation of responsibilities for the radiation protection of service users at the dental practice. Inspectors were satisfied that effective management and leadership was in place at this dental practice with a clear allocation of responsibilities outlined. The undertaking had listed all dentists working at the dental practice as practitioners and also those who were delegated the practical aspects of medical exposures. Inspectors were informed that there were regular informal staff meetings at which issues were discussed including issues regarding radiation protection .

The dental practice did not accept referrals for dental imaging from external sources. The referrer and practitioner were the same person and the practitioner took clinical responsibility for medical exposures. The practical aspects of dental procedures were delegated to appropriate individuals, however, inspectors were informed that these individuals did not generally carry out medical exposures. Inspectors reviewed evidence of radiation safety training provided to staff noting that dental practitioners involved in conducting CBCT scans had received additional training in this area. A clear commitment to the ongoing radiation safety training of staff involved in medical exposures to ionising radiation at the dental practice was evident.

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures was also reviewed if available. Information in relation to the benefits and risks associated with radiation was available to services users and on posters in the clinical rooms.

The dental practice had a policy on justification of medical exposures which clearly set out the process of justification. Inspectors reviewed a sample of records and spoke with staff and found that justification was conducted by appropriate individuals as defined by Regulation 5. In addition, the record of justification was captured for all procedures carried out at the dental practice.

Written protocols for every type of standard dental radiological procedure were available at the dental practice. In addition, staff demonstrated good knowledge of the rationale for imaging and referral guidelines for dental imaging were available to staff. Information related to the exposure was seen in a sample of reports reviewed. In addition, evidence of clinical audit was reviewed by inspections.

The dental practice had access to a medical physics expert (MPE) who was registered with the Irish College of Physicists in Medicine (ICPM) and arrangements were also in place to ensure the continuity of MPE expertise.

Inspectors reviewed documentation outlining the process for the management of accidental and unintended exposures of significant events. Although no incidents relating to accidental or unintended exposure had been identified or reported at the dental practice, inspectors were satisfied that systems were adequate to manage an incident or near miss should one occur.

Overall, inspectors were satisfied that the undertaking had systems in place to ensure the safe and effective delivery of medical radiological exposures at this dental practice and that the failure to meet the requirements of Regulation 6 was an administrative oversight by the undertaking.

Regulation 4: Referrers

From a review of documentation and discussion with management at the practice, inspectors were satisfied that referrals were from staff working within this dental practice, where the referrer and practitioner were the same person. The dental practice did not accept referrals for medical radiological procedures from external sources at the time of the inspection.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for medical exposures conducted at this dental practice.

Judgment: Compliant

Regulation 6: Undertaking

There was a clear allocation of responsibilities to ensure safe and effective care for

those undergoing exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed a radiation safety management flowchart which outlined the structure in place for the radiation protection of service users at the dental practice. Inspectors were informed that there were regular informal staff meetings at which issues including radiation protection could be discussed. Noting that the The James Clinic had a number of local facilities, inspectors found that there was scope to formalise meetings so that information and learning could be shared across facilities ensuring a consistent approach to radiation protection.

However, inspectors had received information prior to the inspection that The James Clinic was conducting medical exposures to ionising radiation for a considerable period of time without notifying HIQA as required by Regulation 6(2). In the first instance, inspectors wrote to The James Clinic to establish if medical exposures were conducted and this was confirmed in writing by the undertaking responsible for the service at The James Clinic. A declaration of undertaking (NF200) form was subsequently submitted following a number of interactions with the undertaking. It was also further determined on the day of inspection that the undertaking had failed to declare that Computed Tomography (CT) exposures were conducted in the facility and this was as a result of an administrative oversight and was corrected immediately following the inspection.

All services that conduct medical exposures must notify HIQA if they are conducting medical exposures as required by Regulation 6. Ongoing attention should be maintained by the undertaking to ensure adherence to all regulatory requirements in respect of medical exposures is maintained.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures was also reviewed if available. Information relating to the benefits and risks associated with radiation was available to services users and displayed on posters in the clinical rooms.

The dental practice had a policy on justification of medical exposures which clearly set out the process of justification. Inspectors reviewed a sample of records and spoke with staff and found that justification was conducted by appropriate individuals as defined by Regulation 5. In addition, the record of justification was captured for all procedures carried out at the dental practice.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that practitioners recognised by the Dental Council took clinical responsibility for all medical exposures to ionising radiation. Furthermore, practitioners with responsibility for CBCT imaging had received specific training and evidence of this training was available for review.

Documentation provided showed that the practical aspects of medical radiological procedures were delegated to appropriate individuals, although, inspectors were informed that these individuals did not generally carry out medical exposures.

In addition, inspectors were satisfied that the optimisation process included the practitioner and MPE and the justification process for all dental exposures carried out at the practice involved the referrer and practitioner.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs were established, reviewed and compared to national DRLs for equipment at this dental practice. MPE dose audits carried out in April and August 2021 were used to calculate local DRLs and these were displayed prominently at the dental practice. Inspectors were informed of a particular procedure which exceeded national DRLs and found that there was scope to strengthen the review process in such an example as required under Regulation 11(6).

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard dental radiological procedure were available at the dental practice. These protocols can provide assurance that dental procedures are carried out in a safe and consistent manner.

Information relating to the medical exposure as required by Regulation 13(2) was available in a sample of reports reviewed.

Staff demonstrated a good knowledge of the rationale for imaging and inspectors were informed that referral guidelines for dental imaging were available to staff at the dental practice.

Inspectors reviewed evidence of clinical audit conducted including justification and

image quality of medical exposures. Clinical audit is an important tool which allows undertakings to identify areas of good practice and areas of improvement to ensure the safe delivery of dental exposures to service users.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in advance of the inspection. Documentation reviewed showed that appropriate quality assurance and performance testing had been implemented for each piece of medical radiological equipment listed in the inventory. Inspectors were satisfied that the undertaking kept equipment under strict surveillance with regard to radiation protection.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed documentation outlining the process for the management of accidental and unintended exposures and significant events. Staff explained the radiation incident management process to inspectors during the inspection and a template for recording incidents was available for review. Although no incidents relating to accidental or unintended exposure had been identified or reported at this dental practice, inspectors were satisfied that systems and awareness of staff were adequate to manage an incident or near miss should one occur.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that a recognised MPE, with up-to-date ICPM professional registration, was available to this dental practice and arrangements were in place to ensure continuity of MPE expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The MPE was involved in dosimetry, optimisation, quality assurance of equipment and provided advice in relation to DRLs. Evidence that the MPE provided in house radiation safety training during April 2021 was also available for review.

Judgment: Compliant

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

Inspectors were satisfied with the documentation reviewed and information provided by staff that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was in line with the level of risk posed at this dental 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	Not Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	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 The James Clinic, Enfield OSV-0007993

Inspection ID: MON-0033758

Date of inspection: 17/08/2021

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 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: An NF200 form was submitted to Hiqa on 13/07/2021. We have confirmed we take Computed Tomography exposures, this was an administrative oversight and a new NF200 form with this correction was later submitted to HIqa.	

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(2)	An undertaking which, on the commencement of these Regulations, is carrying out practices shall notify the Authority, no later than 3 months after the commencement of these Regulations, of such activity, in such form and manner as may be prescribed by the Authority, and may continue such activity pending said notification.	Not Compliant	Orange	13/07/2021