



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Dublin Dentist Clinic (Dublin 1)
Undertaking Name:	Dublin Dentist LTD
Address of Ionising Radiation Installation:	43/44 Lower Dorset Street, Dublin 1
Type of inspection:	Announced
Date of inspection:	10 January 2023
Medical Radiological Installation Service ID:	OSV-0006115
Fieldwork ID:	MON-0038711

About the medical radiological installation:

Dublin Dentist Clinic (Dublin 1) is a dental practice owned by Dublin Dentist LTD. A number of different dental radiological procedures are carried out at the practice. This includes intra-oral radiographs, orthopantomograms (OPG) and cone-beam computed tomography (CBCT).

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 10 January 2023	13:00hrs to 16:00hrs	Kirsten O'Brien	Lead
Tuesday 10 January 2023	13:00hrs to 16:00hrs	Emma O'Brien	Support

Summary of findings

An inspection of Dublin Dentist LTD at Dublin Dentist Clinic (Dublin 1) was conducted by inspectors on the 10 January 2023 to assess compliance against the regulations. On the day of inspection, inspectors visited the X-ray room at the practice and assessed compliance with the regulations relating to the use of intra-oral radiography, orthopantomogram (OPG) and cone-beam computed tomography (CBCT) procedures.

This inspection was carried out because the undertaking had not submitted a regulatory self-assessment questionnaire to HIQA when requested. Following the inspection, an urgent compliance plan was issued to the undertaking outlining areas of risk arising from non-compliances with the regulations. The non-compliances identified in the urgent compliance plan required a timely intervention by the undertaking to ensure the safe delivery of dental exposures at the practice.

The inspectors were informed that all dentists working at the practice were employed by Dublin Dentist LTD. The person identified to HIQA as the designated manager was also the person identified in the *Radiation Safety Procedures* as the radiation protection officer and person in charge but on the day of inspection staff spoken with were unable to clearly describe the specific allocation of responsibility relating to patients and services users. The undertaking must also ensure that responsibility for the protection of patients and service users is clearly allocated to appropriate individuals and this allocation should be documented for clarity, awareness and understanding of all staff, for example, the role of the practitioner in justification.

Inspectors were satisfied that only an individual entitled to act as a practitioner took clinical responsibility for dental radiological procedures at the practice and that the referrer and the practitioner were the same individual for referrals within the practice. While referrals for dental radiological procedures coming from outside the practice (external referrals) were in writing, they did not include the reason for the request, sufficient medical data or a record of justification by a practitioner, all of which is required by the regulations. As a result, inspectors were not satisfied that the referrer or a practitioner was involved in justification of all dental exposures carried out at the practice.

On the day of inspection, inspectors found that a recognised medical physics expert (MPE) had been engaged by the undertaking to provide consultation and advice following the announcement of this inspection in December 2022. Inspectors noted that while an arrangement had been in place previously with an MPE, this arrangement had lapsed in 2021. This lack of continuity of an MPE had resulted in regulatory deficits including the surveillance of the dental radiological equipment.

Quality assurance (QA) testing of dental radiological equipment by an MPE was found to be underway since the 6 January 2023. However, due to issues found

during the testing of the 3D OPG/CBCT equipment, the MPE QA review had not been fully completed by the time of this inspection. Additionally, inspectors found that the last QA testing by an MPE of the dental radiological equipment had been carried out in 2019 and issues with the equipment identified in 2019 had not been addressed by the undertaking. From speaking with staff and reviewing records and documentation provided, inspectors also found that performance testing on a regular basis and preventative maintenance and servicing of dental radiological equipment had not been carried out. Subsequently, the undertaking had not implemented an appropriate programme of assessment of dose.

Inspectors found that diagnostic reference levels (DRLs) were not in use at the practice and had not been reviewed prior to the announcement of the inspection. DRLs for dental exposures were currently being reviewed at the practice by the MPE as part of the current QA review and were found to significantly exceed the national DRLs for cone-beam computed tomography (CBCT) and exceed the national DRLs for orthopantomogram (OPG) procedures. This finding had also been communicated to the undertaking in 2019 by an MPE but no review of doses or corrective actions had been taken by the undertaking.

The undertaking was requested to submit an urgent compliance plan under Regulation 9 and Regulation 14 to address the identified urgent risks. The undertaking's response provided some assurance that the risks identified were being addressed. Additionally, a representative of the undertaking provided an assurance to inspectors that the 3D OPG/CBCT X-ray equipment would not be used to conduct dental radiological procedures until such time as a quality assurance review had been conducted by a registered MPE and the equipment deemed fit for clinical use.

Regulation 5: Practitioners

Inspectors reviewed a sample of records available on the day of inspection and also spoke with staff and dentists working at the practice. Based on the evidence available on the day of inspection, inspectors found that only registered dentists took clinical responsibility for individual dental exposures.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation and records and spoke with staff regarding the management and oversight structures in place at Dublin Dentist Clinic (Dublin 1), in particular the allocation of responsibility for aspects of radiation protection of service users attending the dental practice.

The person notified to HIQA as the designated manager was the person also identified in the *Radiation Safety Procedures* as the radiation protection officer and person in charge in the schedule of key personnel. However, the specific allocation of responsibility relating to patients and services users and the person who maintains oversight of compliance with the regulations for the undertaking was not clear to inspectors on the day of inspection. For example, inspectors found that issues identified with the equipment by an MPE in 2019 had not been addressed by the undertaking and documentation and information requested by HIQA, such as the self-assessment questionnaire, had not been submitted. In addition, staff spoken with on the day of inspection were not clear as to which individual the undertaking had allocated overall managerial responsibility for ensuring the radiation protection of patients and service users at the practice.

Inspectors were also not satisfied that appropriate measures had been put in place by the undertaking to ensure continuity in the allocation of responsibility to an MPE to ensure continuous access to consultation and advice on matters relating to medical physics as required by the regulations. Additionally, based on the evidence observed on inspection, inspectors were not satisfied that justification and optimisation were clearly allocated to, and carried out by, referrers and practitioners at the practice.

The allocation of responsibility for the radiation protection of service users from dental exposures to ionising radiation must be clearly allocated by the undertaking to appropriately recognised individuals. The governance and management arrangements in place to ensure the safe delivery of dental exposures must also be clearly allocated. To ensure clarity, Dublin Dentist LTD should document the allocation of the different aspects and scope of responsibility for all aspects of radiation protection to appropriate individuals at the practice.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

On the day of inspection, a poster was present and signage was observed on the door and also in the dedicated X-ray room to provide information relating to the risks and benefits associated with dental exposures to patients. Inspectors reviewed a sample of records relating to dental radiological procedures conducted at the practice. However, while internal referrals for dental exposures were recorded on an electronic information system as part of the patients' notes, only two external referrals were available for review. Staff spoken with informed the inspectors that they did not keep records relating to external referrals as they were unaware of this requirement of the regulations.

Inspectors found that a dentist, registered with the Dental Council, took clinical responsibility for justifying all internally referred dental radiological procedures, were the referrer and practitioner where the same individual. However, from a review of

the records available to the inspectors on the day of inspection, a record of justification, by practitioners, of referrals from external referrers for dental radiological procedures was not available. While a log book to record what dental exposures had been carried out had been put in place in the days leading up to the inspection, this did not record what practitioner was responsible for justifying the individual dental radiological procedure.

While internal referrals were found to be accompanied by sufficient medical data in the patients' notes to allow the practitioner to justify the procedure, inspectors found that some referrals for internal dental exposures were not always clearly documented and sometimes did not state the reason for requesting a particular procedure. In addition, while the records of external referrals reviewed were in writing, they did not contain the reason for the request and were not accompanied by medical data to allow a practitioner to justify a dental medical procedure.

Justification of a dental exposure to ionising radiation is the decision whether or not to carry out the medical exposure on the basis of benefit to the patient. Justification is an important safeguard for patients and should always take into account the individual characteristics of each patient to ensure that the procedure is the most appropriate option for them and it is important that the principle of individual justification is adhered to for all dental exposures to ionising radiation carried out at the practice.

Judgment: Not Compliant

Regulation 9: Optimisation

On the day of inspection, inspectors did not find evidence that practitioners were involved in the optimisation of all dental radiological procedures, in particular OPG and CBCT examinations. Inspectors also found that Dublin Dentist LTD had not ensured that all doses due to dental exposures were kept as low as reasonably achievable.

Dentists spoken with on the day of inspection indicated that they did not carry out clinical audits to assess the quality of the images obtained. The use of audit and review is important in ensuring the consistent production of adequate diagnostic information and to ensure that the practical aspects of dental radiological procedures are optimised and patient doses are assessed and evaluated in line with the 'as low as reasonably achievable' (ALARA) principle of radiation protection.

As part of QA assessments of the dental radiological equipment in 2019, a review of patient doses was carried out by an MPE. However, despite issues with optimisation of patient doses having been identified to Dublin Dentist LTD by an MPE in 2019, no evidence was available to show that the undertaking had acted on the advice of the MPE to ensure that all dental exposures carried out at the practice were optimised. Subsequently, the same issues relating to optimisation were identified again by an

MPE in 2023. Additionally, despite the findings of the QA assessment in 2019 relating to dose and equipment functionality, no records or evidence available were available on the day of inspection to demonstrate that the undertaking had ensured that patient doses were evaluated. Similarly, no records or evidence was provided to demonstrate that the undertaking had ensured that an appropriate programme of QA for its equipment had been implemented or maintained.

Following the 2023 QA review of equipment, local DRL values were provided to the undertaking on the 10 January 2023. These local DRLs significantly exceeded the national DRLs for CBCT and exceeded the national DRL for OPG procedures. In line with the findings of Regulation 11, the undertaking must take immediate steps to ensure the optimisation of all dental exposures to ionising radiation at the practice.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response provided some assurance that the risk was being addressed.

Judgment: Not Compliant

Regulation 10: Responsibilities

Inspectors were informed that all medical exposures took place under the clinical responsibility of a practitioner, as per Regulation 5. From speaking with staff and dentists working at the practice, inspectors were also informed that only registered dentists carried out the practical aspects of dental radiological procedures.

A sample of records of internal referrals for dental exposures were reviewed on inspection. From this review of internal referrals, inspectors found that persons entitled to act as both the referrer and the practitioner for individual dental exposures were involved in the justification process for dental radiological procedures. However, inspectors were not satisfied that the referrer or a practitioner were involved in the justification process for externally referred dental exposures carried out at the practice. For example, one referral reviewed did not contain information about the patient such as the patient name, the reason for the request or any other medical data. Information about the individual who had referred the patient for the dental radiological procedure was also not available. Additionally, no record of justification by a practitioner was available for the sample of external referrals reviewed on the day of inspection.

Inspectors also found that while an MPE had put forward recommendations for the optimisation of exposures in 2019, these had not been implemented. Additionally, the undertaking had not ensured the continuity of an MPE involvement and contribution to the optimisation of dental exposures, as discussed in Regulations 19 and 20. Furthermore, inspectors were not assured that practitioners were involved in the optimisation process for all dental exposures carried out at Dublin Dentist Clinic (Dublin 1). For example, dentists spoken with on the day of inspection

communicated that they did not carry out measures, such as clinical audit, to ensure that adequate images were consistently obtained. Additionally, no evidence was available on the day of inspection to indicate that practitioners contributed to QA or the evaluation of dose to patients.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Inspectors reviewed documentation and records and found that DRLs were not in use for dental radiological procedures at Dublin Dentist Clinic (Dublin 1). The inspector noted that the MPE was currently reviewing DRLs at the practice as part of the QA review of equipment. However, while local DRLs for intra-oral procedures were found to be less than the national DRLs, local DRLs for CBCT procedures were found to considerably exceed the national DRLs and local DRLs for OPG procedures were found to exceed the national DRLs. The finding relating to the CBCT had also been identified to Dublin Dentist LTD in 2019.

Inspectors found that a review had not been carried out to determine whether the optimisation of dental radiological procedures was appropriate to ensure the protection of patients, as required by the regulations. Additionally, Dublin Dentist LTD had not ensured that appropriate corrective actions had been taken.

The undertaking must ensure that DRLs are used and regularly reviewed at the practice. DRLs are an important measure in ensuring that dental exposures are adequately optimised for the protection of patients. Similarly, where doses are found to exceed DRLs, a review and appropriate corrective actions should be taken without undue delay.

Judgment: Not Compliant

Regulation 13: Procedures

Inspectors found that Dublin Dentist LTD had not established written protocols for standard dental exposures for each type of dental radiological procedure at Dublin Dentist Clinic (Dublin 1). While the manufacturer's manual had been printed off for use for the 3D OPG/CBCT equipment, no written protocols were available for intra-oral exposures. Written protocols are important as they can provide assurance that dental radiological procedures are carried out in a consistent and safe manner at the practice.

On the day of inspection, inspectors reviewed records and documentation and found that information relating to patient exposure did not form part of the report of

dental radiological procedures conducted at the practice. Additionally, inspectors found that referral or selection criteria which included radiation doses were not available to referrers.

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors spoke with the MPE and management at Dublin Dentist Clinic (Dublin 1) on the day of inspection. Documentation and records relating to the dental radiological equipment at the practice were also reviewed. Inspectors were not satisfied that Dublin Dentist LTD had ensured that dental radiological equipment at Dublin Dentist Clinic (Dublin 1) was kept under strict surveillance regarding radiation protection.

Inspectors requested all documentation and records relating to the dental radiological equipment at the practice. Following a review of the documentation provided, inspectors found that a QA programme had not been maintained. While a QA review by an MPE had been carried out in 2019, a subsequent QA review had not been performed until after the announcement of this inspection. Furthermore, issues identified as part of the 2019 QA review had not been addressed by the undertaking and were subsequently noted as part of the current QA assessment.

The inspectors also found that dental radiological equipment at the practice had not been serviced for preventative and maintenance purposes and that no schedule for such services was in place at the time of inspection. To ensure that all dental radiological equipment is maintained in good working condition, regular preventative maintenance and servicing should be carried out in line with best practice guidelines.

The failure of the undertaking to ensure that equipment was kept under strict surveillance and to implement and maintain an appropriate QA programme were identified as areas requiring urgent action by Dublin Dentist LTD. The undertaking provided a written assurance to inspectors that the 3D OPG/CBCT equipment would not be used until such time as an appropriate QA review by an MPE deemed the equipment fit for clinical use. Additionally, under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that this risk was addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors reviewed documentation and other records, including electronic correspondence and spoke with staff. While inspectors found that an MPE had been previously involved and had been available for consultation and advice until 2021, other information reviewed, including records of QA testing, indicated that the involvement of an MPE had then lapsed. No evidence of continuity of medical physics expertise for Dublin Dentist Clinic (Dublin 1) was provided for a period between February 2021 and December 2022.

However, inspectors did note the efforts of Dublin Dentist LTD to engage an MPE following the announcement of the inspection and that an MPE had been successfully engaged by the undertaking in December 2022 to conduct QA testing and to provide advice and consultation on matters relating to radiation physics. However, at the time of inspection, the inspectors did not see sufficient evidence that this arrangement was formalised to ensure the continuity of access for Dublin Dentist LTD to medical physics expertise for consultation and advice on matters as required by the regulations.

Judgment: Not Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors spoke with staff and reviewed documentation and found that Dublin Dentist LTD had recently engaged an MPE to act and give specialist advice on matters relating to radiation protection of service users following the announcement of the inspection. However, while inspectors found that the undertaking had access to an MPE previously until 2021, inspectors were not assured that Dublin Dentist LTD had maintained sufficient arrangements to ensure the appropriate involvement of an MPE for advice and consultation on radiation physics. This finding contributed to other regulatory deficits found on the day of inspection, including, the finding of not compliant with Regulations 9, 11 and 14.

In particular, inspectors were not assured that, prior to January 2023, the undertaking had ensured that an MPE had taken responsibility for dosimetry and contributed to optimisation, including the use and review of DRLs, the performance of QA or the surveillance of the dental radiological equipment at the practice. While records provided to the inspectors following the inspection indicated that an arrangement had been in place previously, annual QA of the equipment or a review of patient doses had last been completed in 2019 and had been overdue prior to the announcement of the inspection. Inspectors also noted that once the recommendations had been provided to the undertaking following the QA review in 2019, Dublin Dentist LTD had not ensured that the MPE continued to provide advice on the medical radiological equipment. Inspectors also found that an MPE had not contributed to the training of practitioners and other staff in relevant aspects of radiation protection.

Judgment: Not Compliant

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

As detailed in regulation 19 and 20, although an MPE was now engaged and involved for advice and consultation, up to the time this inspection was announced the level of the involvement of the MPE was not sufficient to meet the level of radiological risk posed by this service. This had resulted in a number of non-compliances which were identified on the day of inspection.

Judgment: Not Compliant

Regulation 22: Education, information and training in field of medical exposure

Dentists spoken with on the day of inspection indicated to inspectors that they had not undertaken or completed training as prescribed by the Dental Council in CBCT. Records of training in CBCT evidencing compliance with Regulation 22 for the dentists working at the practice were requested but none were provided to the inspectors for review. Therefore, inspectors found that the undertaking had not ensured that practitioners taking clinical responsibility for CBCT exposures at Dublin Dentist Clinic (Dublin 1) had successfully completed training as prescribed by the Dental Council. In order to be compliant with Regulation 22, Dublin Dentist LTD must ensure that practitioners who take clinical responsibility for CBCT have completed training, as prescribed by the Dental Council, and successful completion of such training must be documented and recorded.

Judgment: Not 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 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Not Compliant
Regulation 9: Optimisation	Not Compliant
Regulation 10: Responsibilities	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Not Compliant
Regulation 19: Recognition of medical physics experts	Not Compliant
Regulation 20: Responsibilities of medical physics experts	Not Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Not Compliant
Regulation 22: Education, information and training in field of medical exposure	Not Compliant

Compliance Plan for Dublin Dentist Clinic (Dublin 1) OSV-0006115

Inspection ID: MON-0038711

Date of inspection: 10/01/2023

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	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: It is my responsibility to ensure all issues raised with the equipment by an MPE, gets immediate attention. I am going to create a maintenance check-list, to ensure all equipment is regularly revised and will be performed yearly following on from the feedback from the MPE. The risks of the radiation had been identified and better management for the safely of the patient will be applied. I am going to appoint a training officer to oversee the training recommended by both HIQA and Dental Council. It is very important to me to ensure we are compliant. I have recently appointed a new clinic Manager whom will support me with the above. I do understand it is my responsibility to ensure we are compliant. Self-assessment questioners will be filled out always on time as asked from HIQA.</p>	
Regulation 8: Justification of medical exposures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: External referrals will be available for review at any time. In the best possible way we will keep all the records organised and ready to be reviewed if required. A log book is strictly followed day by day and all the records are being written down, as well as the justification for each radiograph to be taken. A written reason for the radiograph is being documented in the log book and in the computer system.</p>	

Regulation 9: Optimisation	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 9: Optimisation: Optimisation: It is completely unacceptable that the optimisation has not been addressed. It is my absolute priority to address this issue. I am meeting with the MPE on 13th March, I will be present to seek advice on the next steps. It is imperative I reduce the doses of radiation step by step. Once this meeting has taken place, I will update you with my actions to ensure we are compliant. These have been adjusted however it is pre-set therefore I will need to contact the vendor, my expectation they will have an engineer that will come on-site to support in adjusting the level of radiation. This is also going to be addressed with all practitioners, we will document the level of each patient on the clinical cards.</p>	
Regulation 10: Responsibilities	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: Responsibilities: Going forward all referral letters will be examined to establish the reason the X-ray. These letters will be attached to our own records and filed monthly. This is also going to be rolled out with practitioners, I am going to produce a document for this procedure, have all sign to ensure they fully understand the expectation. All Patients will also be logged on our FELQ with additional information of the finding of the radiology X-ray. The clinic manager will oversee the recording of the patient's information to ensure it is accurate. As well as the information about the individual who had referred the patient for the dental radiological procedure.</p>	
Regulation 11: Diagnostic reference levels	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: Diagnostic reference levels: The diagnostic reference levels have been adjusted to the best and the safest doses for the patient to guarantee the best quality of the image with the lowest possible doses applied to each patient. Control of the DRL will be reviewed by MPE on a regular basis. This as mentioned above it is critical we get the correct procedures in place, ensure all practitioners at the clinic fully trained.</p>	

Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: Since the written protocols are important for each radiography to be taken correctly, a written protocol will be printed and placed in the visible placed for the professionals to review it if necessary at all times. These will also be signed off by each practitioner to ensure compliance. A signed master copy will be available upon request.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: Equipment: Since now on there will be a schedule inspection of MPE yearly to provide the best possible outcome and safely to all patients. The equipment used in the practice will be kept under surveillance and if any urgent actions required they will be addressed as soon as possible. A written assurance was provided to HIQA about the X-ray machine (OPG & CBCT) not being used until the problems will be solved.</p>	
Regulation 19: Recognition of medical physics experts	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts: Recognition of medical physics experts: This is our written assurance that we will have MPE scheduled and followed up yearly. It is a very useful organisation that help maintain the safety and controls the speed of radiation both for patients and professionals working at the dental practice. We have appointed an MPE on a 2 year contact, will assure you we will also have a contingency plan for when the contract expires.</p>	
Regulation 20: Responsibilities of medical physics experts	Not Compliant

<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:</p> <p>Responsibilities of medical physics experts: After the inspection of MPE, there was report issued. The doses of X-ray machines were adjusted. As well as MPE, is willing to provide training for the professional at the dental practice, his next available slot is in February/March 2023. The date confirmed is 13th March. We will schedule a training for the practitioners and other staff in relevant aspects of radiation protection. The clinical manager is overseeing what updated training is required in the clinic for all practitioners. We will also utilise our MPE to get the best training.</p>	
<p>Regulation 21: Involvement of medical physics experts in medical radiological practices</p>	<p>Not Compliant</p>
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:</p> <p>Involvement of medical physics experts in medical radiological practices:</p> <p>The number of non-compliances is identified and adequate handling of the inspection is being performed. This is ongoing as mentioned above.</p>	
<p>Regulation 22: Education, information and training in field of medical exposure</p>	<p>Not Compliant</p>
<p>Outline how you are going to come into compliance with Regulation 22: Education, information and training in field of medical exposure:</p> <p>Education, information and training in field of medical exposure: The usage of CBCT at the practice of Dublin Dentist LTD is limited to one specialist doctor, the doctor upon inspection was a general doctor which does not operate with the system of CBCT. Which doesn't explain the required training by Dental Council. We will address this issues as soon as possible. So far XXX was contacted by email about the information requested about the training but so far no replay has been received. There is again an opportunity for the development of our doctors.</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.	Not Compliant	Orange	
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Not Compliant	Orange	01/02/2023

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Orange	01/02/2023
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).	Not Compliant	Orange	01/02/2023
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as	Not Compliant	Orange	

	prescribed in the referral is justified.			
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.	Not Compliant	Orange	
Regulation 9(1)	An undertaking shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.	Not Compliant	Red	20/01/2023
Regulation 9(4)	An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the	Not Compliant	Red	20/01/2023

	practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.			
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Not Compliant	Red	24/02/2023
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Orange	
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Red	24/02/2023

Regulation 11(6)	An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.	Not Compliant	Red	24/02/2023
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	
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	
Regulation 13(3)	An undertaking shall ensure that referral guidelines for medical imaging, taking	Not Compliant	Orange	

	into account the radiation doses, are available to referrers.			
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Not Compliant	Red	27/01/2023
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Not Compliant	Red	27/01/2023
Regulation 14(2)(b)	An undertaking shall implement and maintain appropriate programmes of assessment of dose or verification of administered activity.	Not Compliant	Red	27/01/2023
Regulation 19(9)	An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.	Not Compliant	Orange	
Regulation 20(1)	An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or	Not Compliant	Orange	

	gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (c) of Article 22(4) of the Directive.			
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,	Not Compliant	Orange	
Regulation 20(2)(b)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) gives advice on medical radiological equipment, and	Not Compliant	Orange	
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological	Not Compliant	Orange	

	<p>practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none"> (i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; (ii) the definition and performance of quality assurance of the medical radiological equipment; (iii) acceptance testing of medical radiological equipment; (iv) the preparation of technical specifications for medical radiological equipment and installation design; (v) the surveillance of the medical radiological installations; (vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures; (vii) the selection of equipment 			
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	<p>required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.</p>	Not Compliant	Orange	
Regulation 22(3)	<p>Subject to paragraph (4), the persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection— (a) prescribed by the Dental Council, (b) prescribed by the Irish College of Physicists in</p>	Not Compliant	Red	30/06/2023

	<p>Medicine, (c) prescribed by the Nursing and Midwifery Board of Ireland, (d) prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, or (e) approved by the Radiographers Registration Board under Part 5 of the Health and Social Care Professionals Act 2005, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).</p>			
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