Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Radetal Ltd.
Undertaking Name:	Radetal Ltd.
Address of Ionising Radiation Installation:	Consultant's Private Clinic, Cork University Hospital, Bishopstown Road, Cork
Type of inspection:	Announced
Date of inspection:	02 July 2024
Medical Radiological Installation Service ID:	OSV-0006235
Fieldwork ID:	MON-0042529

About the medical radiological installation (the following information was provided by the undertaking):

The Consultants Private Clinic opened on the campus of Cork University Hospital in 2003. Since September 2003, Radetal Ltd. has provided diagnostic radiology services (in Suite 0.4) to the medical community of the clinic, to the local primary care community in Cork and also to the wider medical community in Munster, including some hospitals. Consequently, referrals are a combination of consultant referrals and general practitioner (GP) referrals. Radetal Ltd. offers plain film X-ray, orthopantomagram (OPG), cone-beam computed tomography (CBCT) and ultrasound services. All radiography staff are experienced and CORU registered, and all imaging is reported by one of 18 specialist consultant radiologists who are employees of Radetal Ltd. The lead radiologist serves as managing director of Radetal Ltd. and also chair of the radiation safety committee.

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, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is 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 2 July 2024	09:30hrs to 14:10hrs	Kirsten O'Brien	Lead
Tuesday 2 July 2024	09:30hrs to 14:10hrs	Kay Sugrue	Support

Summary of findings

An inspection of the X-ray facility operated by Radetal Ltd. at the Consultant's Private Clinic was carried out by inspectors on the 2 July 2024 to assess compliance with the regulations. The X-ray facility consists of one general radiography (X-ray) room which included dental orthopantomagram (OPG) and Cone Beam Computed Tomography (CBCT) equipment. Inspectors visited the X-ray room and reviewed documentation and records from medical radiological procedures for X-ray, OPG and CBCT procedures. Inspectors also spoke with staff and management during this inspection.

From the evidence found on the day of inspection, inspectors were not assured that the undertaking had appropriate measures in place to ensure that medical radiological procedures were only conducted when referred by persons entitled to act as referrers in the regulations. Following this inspection, Radetal Ltd. was required to submit an urgent compliance plan under Regulation 4 to address the non-compliance identified on inspection. The undertaking's response provided an assurance that the risk was adequately addressed.

Inspectors found that only individuals entitled to take clinical responsibility for individual medical exposures acted as practitioners for medical radiological procedures carried out at the facility. Radiographers, registered with CORU (Ireland's multi-profession health regulator), carried out the practical aspects of all medical exposures. However, as outlined under Regulation 6, documentation relating to the allocation of responsibility for practitioners required improvement to ensure the allocation of the different aspects of clinical responsibility was clear. In addition, the undertaking had not allocated responsibility for the implementation of a clinical audit strategy.

Arrangements were found to be in place to ensure the continuity of medical physics expertise at the facility, however some improvements were required on the day of inspection to ensure that a medical physics expert (MPE) fully contributed as required. However, an MPE and practitioner were found to contribute to optimisation of medical exposures at the facility. Diagnostic reference levels (DRLs) were established for medical radiological procedures, however the methodology used for the establishment of paediatric DRLs did not align with best practice and as a result these were not comparable with the national paediatric DRLs.

A quality assurance (QA) programme had been established for the facility, however on the day of inspection radiographer quality control tests had not been carried out in line with the requirements of this programme. Inspectors did note that annual QA by an MPE had been carried out and arrangements were in place regarding the conduct of regular performance testing by the equipment vendor. Similarly, improvements in the oversight of actual or potential accidental or unintentional

exposures was also required to ensure the timely and appropriate mitigation of possible incidents.

Overall on the day of inspection a number of areas of non-compliance with the regulations were identified which must be addressed by the undertaking.

Regulation 4: Referrers

A number of patient records where reviewed on the day of inspection. Inspectors also spoke with staff and management and reviewed documentation relating to the referral process and the conduct of medical exposures at Radetal Ltd. From the evidence available on the day, inspectors were not assured that all referrals for medical radiological procedures carried out at the facility were from referrers defined in Regulation 4. For example, information about the referrer name and address contained on seven referrals reviewed was inconsistent and did not assure inspectors that these written referrals were from an individual entitled to refer as per the regulations. In addition, a written procedure for an imaging protocol for medical exposures referred from individuals not entitled to act as referrers was also found on inspection and inspectors found that this protocol was used for imaging patients referred to the facility based on referrals from individuals not entitled to refer.

Following this inspection, the undertaking, Radetal Ltd. was required to submit an urgent compliance plan in respect of these findings which required urgent action. The undertaking's response provided an assurance that the risk was adequately and promptly addressed following this inspection.

Judgment: Not Compliant

Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed. The inspector also spoke with staff and management working at the facility and found that only individuals entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors spoke with staff and management working at the X-ray facility, and reviewed documentation and other records, to review the governance and management arrangements in place for the safe delivery of medical exposures. Inspectors found that the X-ray facility at the Consultant's Private Clinic was under the governance and management of Radetal Ltd. The designated manager reported directly to the managing director of Radetal Ltd. Inspectors were informed that the managing director was the undertaking representative for Radetal Ltd., and that the individual carrying out this role rotated each year.

Inspectors reviewed the terms of reference and minutes for the radiation safety committee (RSC). The RSC was chaired by the managing director who was the consultant radiologist in charge, and membership of the RSC included the designated manager, the radiography services manager and an MPE. The RSC's terms of reference contained information about organisations which no longer operate and inspectors found that this document was due for update in 2019, yet it had not been reviewed on the day of inspection.

Overall, inspectors noted that a number of documents reviewed as part of this inspection did not reflect the change in regulations relating to medical exposures in 2019 and also did not align with day-to-day practice in the facility. Inspectors found from the evidence gathered, that documentation of the different aspects of clinical responsibility needed to be strengthened to ensure that the allocation is clear and understood by all members of staff and management to support staff in carrying out their roles and responsibilities. In particular, the undertaking must improve the systems in place to ensure that medial exposures are only carried out once the practitioner responsible for justifying the medical exposures is satisfied that the referral is justified. In addition the undertaking must improve oversight of the management and review of documentation at the facility, including written protocols for medical exposures.

From a review of documentation and speaking with staff and management, inspectors found that some aspects regarding the allocation of responsibilities were met. For example, inspectors were satisfied that the management of Radetal Ltd. had arrangements in place to ensure the appropriate involvement of medical physics expertise at the facility. However several aspects of allocation required action to comply with the requirements of Regulation 6(3). For example, from the sample of referrals viewed and discussed previously, inspectors were not assured that appropriate arrangements were in place to ensure that responsibility for justification always included a person entitled to act as a referrer as detailed under Regulation 4: Referrers.

Inspectors also found that the allocation of responsibility for the establishment and implementation of a clinical audit strategy, and contingency arrangements for other aspects of radiation protection, such as ongoing QA of medical radiological equipment, required improvement and should be allocated to appropriate personnel within the undertaking.

In order to come into compliance with the requirements of this regulation the undertaking must put measures in place to ensure that there is stronger oversight of

information contained in its policies, procedures and other documentation. Furthermore, the undertaking must ensure that the allocation of responsibility for radiation protection is clearly documented to appropriate individuals for all aspects of medical exposures.

Judgment: Not Compliant

Regulation 8: Justification of medical exposures

The inspectors observed information about the benefits and risks associated with the radiation dose from medical exposures available to patients in the form of posters and information leaflets in the X-ray waiting area. A sample of referrals were reviewed by the inspectors who found that these were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Inspectors spoke with practitioners who explained how medical exposures were justified in advance and how this justification was recorded. A record of justification in advance by a practitioner was found on all records reviewed as part of this inspection. However, from speaking with staff and management, inspectors found that processes to facilitate practitioners to satisfy themselves that the procedures were justified before being carried out were not in place. To strengthen the justification process the undertaking should have a process in place to address queries regarding the appropriateness of referrals and or the identification of the referrer to ensure the procedures prescribed in the referral are justified.

In order to come into full compliance with this regulation, Radatel Ltd. must ensure that they have systems in place to assure themselves that medical radiological procedures are only carried out when a practitioner is satisfied that the referral is justified.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that a person entitled to act as a practitioner took clinical responsibility for all individual medical exposures. Additionally, individuals entitled to act as practitioners and an MPE were involved in the optimisation of medical radiological procedures. CORU registered radiographers carried out the practical aspects of all medical exposures conducted at the facility.

However, while a practitioner was involved in the justification process for all medical radiological procedures, inspectors were not satisfied that a person entitled to act as

a referrer was involved in the justification of a number of medical exposures. Further evidence in relation to this finding is detailed under Regulation 4: Referrers.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

The inspectors reviewed documentation submitted in advance of the inspection and also spoke with staff and management to determine how DRLs were established, used and reviewed at the X-ray facility operated by Radatel Ltd. Local facility DRLs had been established, however the inspectors observed that while local facility DRLs were available in the Radiation Safety Procedures Manual, only national DRLs were available for use in the control area of the X-ray room on the day of inspection. Therefore, there was a lack of assurance that facility DRLs were applied in day-to-day practice.

Furthermore, the facility's paediatric DRLs had not been established using the appropriate methodology which includes the use of pre-determined weigh categories in line with national and international best practice. As a result, the paediatric DRLs were not comparable to available national DRLs.

Judgment: Not Compliant

Regulation 13: Procedures

The inspectors reviewed a sample of medical radiological procedures and found that information relating to patient exposure did not form part of the report of these medical radiological procedures as required by Regulation 13(2).

The inspectors found that written protocols were established for a number of standard medical radiological procedures, however these did not include paediatric procedures. In addition, these written protocols included loose pages and had hand written updates which did not assure inspectors that appropriate oversight was in place by the undertaking. When reviewing protocols the undertaking should ensure that the protocols are up-to-date, fully approved for use and consider optimisation for all procedures.

In addition, a clinical audit strategy was not in place on the day of inspection. While a reference to the undertakings approach to clinical audit was included in the Radiation Safety Procedures, this was limited and did not include all essential elements as required by the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* which was published in

November 2023. Inspectors also noted that only one clinical audit had been carried out in the last 12 months and a clinical audit schedule was not in place.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory was provided in advance of the inspection. Inspectors found that an ongoing assessment of doses was carried out and that information about the radiation doses at the facility was reviewed by a medical physicist periodically.

Inspectors found that a QA programme had been established and documentation outlining the performance tests for both pieces of X-ray equipment was included. The inspectors noted that the equipment's acceptance testing had been completed by a medical physicist before first clinical use. The QA programme included an annual QA assessment by an MPE and maintenance testing by the equipment vendor. However, from reviewing records and speaking with staff on the day of inspection, inspectors found that routine quality control testing was not performed in line with the established QA programme.

To ensure that gaps in regular performance testing do not occur, management must ensure that they have appropriate arrangements in place to ensure that sufficient contingency arrangements are in place to kept medical radiological equipment under strict surveillance regarding radiation protection.

Judgment: Substantially Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in the X-ray waiting area at the facility. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status, where relevant, in line with the regulations. Inspectors reviewed a sample of referral records and found that an inquiry regarding the pregnancy status of the patient had taken place, where required, and this was recorded in writing.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors spoke with staff and management about the process for reporting and were informed that a limited number of actual or potential accidental of unintended exposures have been reported at the facility. On the day of inspection, inspectors found that the process of oversight by the undertaking to ensure that mitigation of possible incidents should be improved.

Staff and management informed the inspectors that information relating to accidental and unintended exposures was kept on a computer in the control area. However, inspectors found that incident report forms were also stored in hard copy in binders when reviewing documentation and records as part of the inspection. Incidents were also only reviewed by the undertaking at the RSC and inspectors did not find any evidence that a system was in place to ensure that analysis or trending was carried out.

In order to be fully compliant with this regulation, Radetal Ltd. must ensure that it has appropriate oversight of actual or potential accidental or unintentional exposures to ensure appropriate mitigating actions can be put in place when required.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, management at Radetal Ltd. had ensured the continuity of medical physics expertise at the facility. Inspectors reviewed a service level agreement and spoke with management and the medical physicist to determine the arrangements in place on the day of inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspectors reviewed documentation and spoke with staff and management at the facility to determine the arrangements in place to ensure that the involvement and contribution of medical physics expertise was in line with the requirements of Regulation 20. On the day of inspection an MPE was found to be involved in QA programmes, acceptance testing and dosimetry. However, inspectors were not assured that an MPE contributed to all aspects as required in Regulation 20(2), for example, the training of practitioners and other staff in relevant aspects of radiation protection.

Judgment: Substantially Compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices
On the day of inspection, inspectors were satisfied from the evidence reviewed that an MPE was involved for the most part at the X-ray facility in line with the radiological risk. However, some improvements were required to ensure that an MPE contributes to all aspects as required by Regulation 20.
Judgment: Substantially 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, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Not Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Compliance Plan for Radetal Ltd. OSV-0006235

Inspection ID: MON-0042529

Date of inspection: 02/07/2024

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, as amended.

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 4: Referrers	Not Compliant
Outline how you are going to come into compliance with Regulation 4: Referrers: 1. Immediate suspension of the referral pathway of concern was undertaken the day of the inspection 2. New policy on accepting referrals drafted 4 July 2024, which specifies that the name, address, signature and Irish Medical Council number of referrer to be legible on all referrals. All routine referrers were informed of this in writing on 5 July 2024. 3. On 5 July 2024 all staff in the clinic were informed of the updated referral policy. At this meeting a referral audit was also discussed, and it was agreed that a referral audit would be planned and completed in the coming weeks. This audit is now complete. A repeat audit will be performed 3 months after this being instituted – October 2024. 4. On 9 August 2024 a separate internal review of all referral data for the previous 18 months established that there were no other cases similar to the one that was identified in the HIQA audit (where it was unclear if the signature and contact details were from the correct referrer). 5. As a result of the audit and review findings, the draft policy on accepting referrals was provisionally adopted, and any referral received that is unclear or incomplete (for example the IMCN of the referrer is not stated) is now returned to the referrer for amendment. This policy, which has also been updated for paediatric referrals will be reviewed and adopted at the next RSC meeting.	
Regulation 6: Undertaking	Not Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: 1. The RSC terms of reference will be reviewed and updated at the next RSC meeting. 2. As a result of the referral audit and internal review findings, the draft policy on accepting referrals was provisionally adopted, and any referral received that is unclear or	

incomplete (for example the IMCN of the referrer is not stated) is now returned to the referrer for amendment. This policy, which has also been updated for paediatric referrals will be reviewed and adopted at the next RSC meeting.
3. All procedures for Medical Exposure were reviewed and complied in a new list following the HIQA audit by the Radiation Safety Committee. Any procedures no longer carried out were removed from the list or noted as no longer carried out in this undertaking. Paediatric Procedures were included in the list. This list will be reviewed and approved at the next meeting of the Radiation Safety Committee, and will be readily available for all Radiography Staff in the X-Ray room. A copy of the draft list is attached with this reply.
4. Following the publication by HIQA of National procedures for Clinical Audit of Radiological Procedures in November 2023, the RSC reviewed this report at the meeting in March 2024, where it was agreed that (a) Radetal adopts a formal clinical audit strategy based on the structure/process/outcomes approach as advocated by HIQA (b) Radetal establishes a clinical audit cycle (c) Radetal updates the Radiation Safety Procedures Manual to include the new audit strategy. Work is underway to draft a clinical audit strategy and a clinical audit cycle, and will be reviewed at the next RSC meeting.
5. Radetal reviewed contingency arrangements for the QA program in the event of the absence of key staff, and made contractual arrangements with the acting RSM that the regular ongoing aspects of radiation protection (such as the QA program and equipment servicing) is continued as normal without any interruption. These contractual arrangements will also apply to the permanent new RSM, and also to any future locum who is appointed as acting RSM.

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
The MPE advised that Radetal formally delegate responsibility for justification of exposures to the duty Radiographer, who in turn contacts the duty Radiologist in the event of a query. The Radiation Safety Procedures Manual will be updated to reflect this arrangement at the next RSC meeting.

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
1. As a result of the referral audit and internal review findings, the draft policy on accepting referrals was provisionally adopted, and any referral received that is unclear or

incomplete (for example the IMCN of the referrer is not stated) is now returned to the referrer for amendment. This policy, which has also been updated for paediatric referrals will be reviewed and adopted at the next RSC meeting.
2. All procedures for Medical Exposure were reviewed and complied in a new list following the HIQA audit by the Radiation Safety Committee. Any procedures no longer carried out were removed from the list or noted as no longer carried out in this undertaking. Paediatric Procedures were included in the list. This list will be reviewed and approved at the next meeting of the Radiation Safety Committee, and will be readily available for all Radiography Staff in the X-Ray room. A copy of the draft list is attached with this reply.

Regulation 11: Diagnostic reference levels	Not Compliant

Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:
1. The Local DRLs (as specified in appendix 6 of the Radiation Safety Procedures Manual) are now displayed in laminated form in the room with the national DRLS, and are available for all staff to check.
2. National DRLs will be used until the next meeting of the RSC when the Paediatric DRLs will be reviewed. An audit of paediatric DRLs will be considered using weight categories.
3. For all future paediatric referrals (patients under 18), the referrer will be instructed to note the weight of the patient on the referral.
4. A weighing scales will be installed in the X-Ray room and the weight of patients will be recorded if the DRLs used in the exam are significantly in excess of the national DRL.

Regulation 13: Procedures	Not Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
1. Reg 13(1): All procedures were reviewed and compiled in a new list following the HIQA audit by the acting RSM and chair of the RSC. Any procedures no longer carried out were removed from the list or noted as no longer carried out in this undertaking. Paediatric Procedures were included. This list will be reviewed and approved at the next meeting of the Radiation Safety Committee, and will be readily available for all Radiography Staff in the X-Ray room.

2. Reg 13(2): Information relating to all the patient exposure is now present on all radiological reports from the clinic.
"Please note: Ionising Radiation is not used in Ultrasound or MRI examinations. All other

examinations involve the patient having medical exposure to ionising radiation. Information relating to this exposure can be found at: (https://www.hse.ie/eng/about/who/acute-hospitals-division/radiation-protection/radiation-doses-received-during-medical-procedures/). The patient/doctor can also contact the Radiology Department for the specific radiation dose associated with the procedure."

3. Reg 13(4): Following the publication by HIQA of National procedures for Clinical Audit of Radiological Procedures in November 2023, the RSC reviewed this report at the meeting in March 2024, where it was agreed that (a) Radetal adopts a formal clinical audit strategy based on the structure/process/outcomes approach as advocated by HIQA (b) Radetal establishes a clinical audit cycle (c) Radetal updates the Radiation Safety Procedures Manual to include the new audit strategy. Implementation was delayed with staffing issues and work is underway to draft a clinical audit strategy and a clinical audit cycle, and will be reviewed at the next RSC meeting. This strategy will better align with the national audit procedure. This will be implemented by the end of 2024 and will be measureable by way of relevant audits and reports.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
The monthly and bi-monthly QC testing of equipment was reviewed and is now re-arranged as a priority. The Acting RSM is now contractually responsible for the QC testing, and this responsibility will pass to the new permanent RSM (who joins Radetal Ltd in late Autumn). The MPE has arranged a date (Aug 22) for training the Acting RSM in the use of the test equipment for the monthly X-Ray QC test. The RSC will review this issue at the next meeting and adopt a system to ensure that gaps in QC testing will not re-occur.

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
1. Formally review every incident as soon as possible, and maintain records of the action taken and any follow-up required at that point.
2. Establish a system for analysing incidents and identifying trends, such as repeated

issues from a single referrer or staff member.
3. Maintain all records of incidents, follow-up and trending in one system (computer).

Regulation 20: Responsibilities of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts:
The MPE has arranged a date (Aug 22) for training the Acting RSM in the use of the test equipment for the monthly X-Ray QC test. Also, the MPE has recommended that all practitioners and all staff undertake training in Radiation Protection, and advises that there are two appropriate course available on-line which are as follows:
1. An Introduction to Radiation Safety Awareness
2. Ionising Radiation and Protecting Our Patients in the Healthcare Setting The RSC will review this recommendation at the next meeting and arrange access to these courses for all practitioners and staff.

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

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
The MPE (as a member of the RSC) will review and approve the updated (draft) list of medical procedures, and if any other procedure not included in this list arises in any context in future, the MPE will be consulted for advice about the procedure. This may occur, for example, in the case of a new referrer who requests examinations not already included in the list of procedures, or in the case of special procedures for clinical trials.

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 4(1)(a)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,	Not Compliant	Red	17/07/2024
Regulation 4(1)(b)	A person shall not refer an individual for medical radiological procedures to a	Not Compliant	Red	17/07/2024

	practitioner unless the person referring ("the referrer") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),			
Regulation 4(1)(c)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),	Not Compliant	Red	17/07/2024
Regulation 4(1)(d)	A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or	Not Compliant	Red	17/07/2024
Regulation 4(1)(e)	A person shall not refer an individual	Not Compliant	Red	17/07/2024

	for medical radiological procedures to a practitioner unless the person referring ("the referrer") is a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner.			
Regulation 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	17/07/2024
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	Not Compliant	Orange	31/10/2024

	of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.			
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 prescribed in the referral is justified.	Not Compliant	Orange	31/10/2024
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Orange	31/10/2024
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	Not Compliant	Orange	31/10/2024

	paragraph (1) where available.			
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	31/10/2024
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	19/08/2024
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Not Compliant	Orange	31/12/2024
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	31/10/2024
Regulation 14(2)(a)	An undertaking shall implement and maintain appropriate quality assurance programmes, and	Substantially Compliant	Yellow	31/10/2024
Regulation 17(1)(c)	An undertaking shall ensure that	Substantially Compliant	Yellow	31/10/2024

	for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following: (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	Substantially Compliant	Yellow	31/12/2024

	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 required to perform radiation protection measurements; and (viii) the training of practitioners and other staff in relevant aspects of radiation protection.			
Regulation 21(2)(c)	In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and	Substantially Compliant	Yellow	31/10/2024

	advice on matters relating to radiation protection concerning medical exposure.			