



**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:	Pembroke Dental Bagenalstown
Undertaking Name:	Granby Medical Ltd
Address of Ionising Radiation Installation:	Kilree Street, Bagenalstown, Carlow
Type of inspection:	Announced
Date of inspection:	22 January 2024
Medical Radiological Installation Service ID:	OSV-0008114
Fieldwork ID:	MON-0039938

About the medical radiological installation:

Pembroke Dental Bagenalstown is a dental surgery location, that opens on a part-time basis. There are currently four staff offering a range of general dental services including orthodontics to the public. There are two X-ray machines in the service, an intra oral machine which is operational and an orthopantomogram machine which is not in use.

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
Monday 22 January 2024	11:30hrs to 13:40hrs	Margaret Keaveney	Lead

Summary of findings

An inspection of Pembroke Dental Bagenalstown was completed on 22 January 2024, in order to assess compliance with the regulations and to follow up on a self-assessment questionnaire completed by the undertaking's management team in April 2022. Granby Medical Ltd. declared as the undertaking for the medical radiological services in Pembroke Dental Bagenalstown, from 01 October 2021.

During the inspection, staff described the allocation of roles and responsibilities for the radiation protection of service users in the dental service. The inspector was informed that the dental service did not accept referrals for medical radiological exposures from external sources and that dentists employed by the undertaking had been allocated the roles of referrer and practitioner, and in practice were the same person. The inspector was also informed that only persons allocated the role of practitioner took clinical responsibility for medical exposures. However, some action was required in the documenting of these allocated roles so that they accurately reflected the practice in the service and strengthened the radiation protection of service users. This is further discussed under Regulation 6 below.

All referrals reviewed by the inspector 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 the inspector 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 on posters in the waiting area.

The management team had developed a *Radiation Safety Policy* which included guidance for referrers and practitioners on the justification of medical exposures. Although staff who spoke with the inspector clearly described the justification process, a review of a sample of records and clinical audit results showed that the record of justification was not captured for all procedures carried out at the dental service. This is further discussed under Regulation 8 below.

The inspector also noted that diagnostic reference levels (DRLs) had been established in January 2024, and were in use when completing exposures for adult service users. However, the inspector was not provided with evidence that these DRLs were regularly reviewed. From a review of documentation and discussions with staff, the inspector also observed that the undertaking could enhance the radiation protection of paediatric service users by ensuring that practitioners were guided and supported in optimising medical exposures to paediatric service users. This is further discussed under Regulation 6 below.

Written protocols for standard dental radiological procedures and referral guidelines were available at the dental practice, and staff demonstrated good knowledge of the rationale for imaging. However, the inspector noted that information related to the exposure was not included in a sample of imaging reports reviewed. This gap had

been identified by the management team through recent clinical audits, and the inspector was informed of an action plan to address this gap, that was being discussed with the medical physics expert (MPE).

The inspector was informed that there were regular staff meetings at which radiation protection issues were discussed, including clinical audit results. Completing clinical audits and sharing the audit results and learning was identified as effective management and good practice in this dental service.

The dental service was equipped with two medical radiological equipment units, however, the inspector was informed and the records showed that only the intraoral unit was currently in use. Although the inspector reviewed quality assurance (QA) reports for the radiological equipment completed in January 2024 by the MPE, the management team could not provide the inspector with records of equipment QA completed between October 2021 and January 2024.

A review of the January 2024 QA record showed that, although deemed safe for clinical use, there was a recommendation that the undertaking replace equipment, as routine, within the next two years. The inspector was informed that replacement equipment had been ordered and was due to be installed two weeks following the inspection. This proactive approach to the advice of the MPE, by the undertaking, was identified as a good radiation protection measure.

On the day of the inspection, the inspector noted that the undertaking was compliant with Regulations 19, 20 and 21 and had ensured the continuity of medical MPE expertise and appropriate involvement in the service, as per these regulations.

The inspector reviewed documentation which outlined 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, the inspector was satisfied that systems were adequate to manage an incident or near miss should one occur.

Overall, notwithstanding the gaps in compliance identified during this inspection, the inspector was satisfied that Pembroke Dental Bagenalstown had systems in place to ensure the safe and effective delivery of dental radiological procedures to service users.

Regulation 4: Referrers

From discussions with staff and the review of a sample of service user records, the inspector was satisfied that referrals for medical exposures to ionising radiation were from dentists working within Pembroke Dental Bagenalstown. This met the requirements of Regulation 4. At the time of the inspection, the dental service did not accept referrals for medical radiological procedures from external sources.

Judgment: Compliant

Regulation 5: Practitioners

The inspector was satisfied that only those entitled, under Regulation 5, to act as practitioner were taking clinical responsibility for medical exposures completed in the Pembroke Dental Bagenalstown, which was namely dentists employed by the undertaking.

Judgment: Compliant

Regulation 6: Undertaking

Granby Medical Ltd. had notified HIQA that they were the undertaking for Pembroke Dental Bagenalstown from 01 October 2021. From speaking with staff in the service, the inspector was assured that key personnel were aware of their allocated roles and responsibilities in the radiation protection of service users.

Notwithstanding that the undertaking had allocated roles and responsibilities to appropriate persons as per the Regulations 4 and 5, improvements in the documentation of these roles and their responsibilities were required by the undertaking in order to come into compliance with Regulation 6. For example;

- The management team had developed a *Radiation Safety Policy* which allocated the roles of referrer and practitioner to dentists working in Pembroke Dental Bagenalstown. However, this policy required review to ensure that it reflected the practice within this facility. For example, although the policy stated that radiographers or suitably qualified dental nurse/hygienist may also take an exposure, on the day of the inspection none were employed by the undertaking. A clear allocation of roles and responsibilities, specific to this facility, is a key element of radiation protection of service users.
- On the day of the inspection, the inspector was informed by staff that medical exposures of ionising radiation were completed for paediatric service users when required. However, from a review of the *Radiation Safety Policy* and other documentation, the inspector noted that the responsibilities of the undertaking, referrers and practitioners with regard to the radiation protection of this cohort of service users was not documented. For example, good radiation protection should include specific optimisation practices for this cohort of service users.

On the day of the inspection, the inspector also noted that some allocated responsibilities were not being fulfilled within the service. For example, the *Radiation Safety Policy* stated that the undertaking was responsible for ensuring that a

biennial quality assurance programme for radiological equipment was implemented. However, from a review of documentation and discussions with staff, the inspector noted that this programme had not been completed biennially since the undertaking had declared to HIQA in 2021.

While some gaps in compliance were identified on the day of the inspection, the inspector was satisfied that they did not pose a current risk to the safety of service users undergoing medical exposures in Pembroke Dental Bagenalstown.

Judgment: Substantially Compliant

Regulation 8: Justification of medical exposures

From the sample of four service user referrals reviewed, the inspector was satisfied that referrals were available in writing, stated the reason for the request and were accompanied by sufficient medical data to facilitate the practitioner when considering the risks and benefits of the exposure. Staff also demonstrated to the inspector that previous diagnostic information from procedures was reviewed if available, and that enquiries were made to service users to determine if they had recent imaging in other dental services. Information relating to the benefits and risks associated with radiation was made available to service users in the waiting area of the dental service.

The management staff had developed a *Radiation Safety Policy* which informed practitioners of the requirement to justify medical exposures. However, the inspector noted from the review of the sample of service user records and from clinical audits, carried out by the management team in October 2023, that justification in advance was not captured for all individual medical exposures carried out at the dental practice. Notwithstanding the findings of not compliant with Regulations 8(8) and 8(15) on the day of the inspection, the inspector observed that following the recent clinical audits, the management team had raised staff awareness on the requirement to justify in advance of all individual medical exposures, and that improvements to this regulatory requirement had been made within the service. Although recognising the gaps in compliance with this regulation, the monitoring of the justification process was identified as an area of good practice by the management staff as it contributed to the radiation safety of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

The inspector was satisfied that a practitioner took clinical responsibility for all medical exposures to ionising radiation completed in Pembroke Dental Bagenalstown.

The inspector was also satisfied that optimisation processes for medical radiological procedures involved the practitioner and MPE, and that the justification process for these procedures involved the referrer and practitioner, who was the same person.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

In January 2024, the undertaking, Granby Medical Ltd., had established, and compared to national levels, a DRL for adult service users, as required by Regulation 11. This local DRL was below national levels, and therefore indicated that service users were receiving a safe service. It was prominently displayed in the clinical room of the dental service, for easy access and use by the practitioner during the optimisation process.

Although a record of DRL review from January 2024 was available, the inspector was not provided with evidence that this DRL was regularly reviewed, as required by the regulations. The regular review of DRLs is required to ensure that the optimisation of protection for service users is adequate.

Judgment: Substantially Compliant

Regulation 13: Procedures

The inspector noted that a written protocol for standard dental radiological procedures, carried out on the intraoral unit in Pembroke Dental Bagenalstown, was available to staff as required by Regulation 13(1). Staff who spoke with the inspector demonstrated an awareness of this protocol, in particular the details pertaining to optimisation of medical exposures, which provided assurance that medical radiological procedures are carried out in a safe and consistent manner in the service.

The inspector also reviewed evidence of clinical audit carried out at Pembroke Dental Bagenalstown, which had identified areas of good practice and also some areas for improvement. The inspector noted that the management staff had devised an action plan for the areas requiring improvement, and had sought the advice of the MPE on this plan. They had also informed relevant staff in the service of the audit findings and action plan. This was identified as an area of good practice within the service.

The inspector also noted that referral guidelines for medical imaging were developed for relevant staff in the dental service as required by Regulation 13(3). The management staff informed the inspector that these guidelines formed part of the training and induction information available to staff. However on the day of the inspection, staff who spoke with the inspector were not familiar with these documented guidelines. In order to enhance the radiation protection of service users, appropriate referral criteria training should be included in radiation protection training for staff, which the undertaking should avail of from the MPE.

From the sample of reports on medical radiological procedures reviewed, the inspector noted that information relating to the medical exposure did not form part of the report, as required by Regulation 13(2). The management staff had identified this gap from clinical audits completed, and had liaised with the MPE to develop an action plan to comply with the regulation. However, on the day of the inspection, the undertaking was found to be not compliant with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspector reviewed records of performance testing, completed in January 2024, for the medical radiological equipment in Pembroke Dental Bagenalstown and was satisfied that the equipment was now kept under strict surveillance as required by Regulation 14(1). The inspector also received an up-to-date inventory of medical radiological equipment in advance of the inspection, which satisfied the requirements of Regulation 14(10).

From a review of the undertakings *Radiation Safety Policy*, the inspector saw that radiation protection of all persons undergoing a medical radiological exposure in the service was allocated to the undertaking's management staff and that the quality assurance programme for the equipment was to be completed every two years. The undertaking had taken ownership of the service in October 2021, however records of performance testing from October 2021 to January 2024 were not available to the inspector, and therefore the inspector was not satisfied that testing was carried out on a regular basis as required by Regulation 14(3). Due to gaps in the records pertaining to the equipment, the undertaking was also assessed as not compliant with Regulation 14(11).

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

The inspector noted that the process for the management of accidental and unintended exposures and significant events was included in the *Radiation Safety Policy*, developed by the undertaking's management staff. The inspector spoke to staff who outlined the radiation incident management process and a report form for recording incidents was available for review.

Although no incidents relating to accidental or unintended exposure had been identified or reported at Pembroke Dental Bagenalstown, the inspector was satisfied that there were adequate systems and staff awareness to manage an incident or near miss, involving a medical exposure to ionising radiation, should one occur.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

From speaking with the management staff and the MPE, the inspector was satisfied that adequate arrangements were in place to ensure the continuity of medical physics expertise at Pembroke Dental Bagenalstown, as required by Regulation 19. From a review of documentation, the inspector noted that the MPE had a formal arrangement in place with the service's management staff which ensured appropriate access to their expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspector reviewed the professional registration certificate of the MPE providing medical expertise to Pembroke Dental Bagenalstown, and noted that the MPE also acted as the radiation protection adviser for the service and thereby satisfied the requirements of Regulation 20(3).

The inspector also reviewed documentation that evidenced that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). The inspector noted that the MPE had undertaken a range of responsibilities within the dental service, as outlined in Regulation 20(2). For example, they took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to the definition and performance of a quality assurance programme. The MPE was also involved in optimisation including establishing DRLs.

The MPE informed the inspector that they were liaising with the undertaking's management team to provide online radiation protection training to staff in the dental service and that they were also available to advise on any radiation protection matters as required.

Judgment: Compliant

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

On the day of the inspection, the inspector was satisfied that an MPE was appropriately involved in Pembroke Dental Bagenalstown, and that the level of involvement was commensurate with the radiological risk posed by the dental practice as required by Regulation 21.

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	Substantially Compliant
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Not 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 Pembroke Dental Bagenalstown OSV-0008114

Inspection ID: MON-0039938

Date of inspection: 22/01/2024

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 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	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The Pembroke Dental Radiation Safety Policy has already been amended to reflect the local practice in Bagenalstown in order to clarify the allocation of roles and responsibilities specific to the Bagenalstown location as discussed on the day of inspection with the inspecting officer. The biennial QA programme is now on a strictly monitored timetable, agreed with the management team and MPE, to ensure the QA programme is not delayed in the future.</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: An inhouse continuing education programme has been further developed and is ongoing for practitioners to ensure that the justification of medical exposures is further developed and in line with best practice for end users.</p>	
Regulation 11: Diagnostic reference levels	Substantially Compliant

<p>Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: In conjunction with our MPE, we are introducing a review system for DRL'S which will be part of our audit programme. As part of our ongoing continuous professional development programme for practitioners, we are introducing an education module which discusses the importance of DRL'S and their review in practice.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: A proposed action plan is in the final developmental stage with our MPE and will be actioned within 4 weeks at local level amongst management team and practitioners. A template ionising radiation prescription /report form is in final development which will include the required information relating to the medical ionisation exposure to patients and this will become the standard template to be used by practitioners in the future. Refresher training has already been carried out by practitioners in regards to referral criteria guidelines for medical imaging and this will continue to be part of induction training also.</p>	
Regulation 14: Equipment	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 14: Equipment: The QA performance is now in a strict calendar schedule, ensuring this non-compliance will not be repeated. A new intraoral machine has been purchased and we are awaiting installation from our supplier.</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.	Substantially Compliant	Yellow	30/03/2024
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	Substantially Compliant	Yellow	30/03/2024

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	30/05/2024
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 paragraph (1) where available.	Substantially Compliant	Yellow	30/06/2024
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	30/05/2024
Regulation 14(3)(b)	An undertaking shall carry out the	Not Compliant	Orange	01/03/2024

	<p>following testing on its medical radiological equipment, performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.</p>			
Regulation 14(11)	<p>An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.</p>	Not Compliant	Orange	01/03/2024