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:	Mobile Medical Diagnostics Ltd.
Undertaking Name:	Mobile Medical Diagnostics Ltd.
Address of Ionising Radiation Installation:	Unit D1 Dunshaughlin Business Park, Dunshaughlin, Meath
Type of inspection:	Announced
Date of inspection:	25 June 2024
Medical Radiological Installation Service ID:	OSV-0005948
Fieldwork ID:	MON-0042300

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

Mobile Medical Diagnostics Ltd. provide a swift access X-ray service to various community-based locations including nursing homes, community nursing units, individual's private dwellings and primary care centres. The service has been in operation since 2017 and offers a high value service to our patients and the wider health system. Our team of radiographers are CORU registered. Our radiologist reports are completed by Irish Medical Council (IMC) registered radiologists. We accept referrals from all IMC registered physicians with the majority received from general practitioners (GPs) however consultants and non-consultant hospital doctors (NCHDs) also refer to the service from hospices and transitional care settings. The service has been greatly received to date due to preventing many hospital transfers for elderly and cognitively impaired service users.

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 25 June 2024	10:00hrs to 15:55hrs	Kirsten O'Brien	Lead
Tuesday 25 June 2024	10:00hrs to 15:55hrs	Emma O'Brien	Support

Summary of findings

An inspection of Mobile Medical Diagnostics Ltd. was carried out by inspectors on the 25 June 2024. Mobile Medical Diagnostics Ltd. provide a mobile X-ray service to patients across different locations nationwide including nursing homes, primary care services and patients' own residences, as required. The company operates eight mobile X-ray units which were based in different locations around Ireland. On the day of inspection, inspectors spoke with staff and management and reviewed the mobile X-ray equipment based in Co. Meath.

The governance and management arrangements in place to ensure the safe delivery of medical exposures were reviewed on the day of inspection for all medical radiological equipment operated by Mobile Medical Diagnostics Ltd. The designated manager with responsibility for the radiation protection of service users was the director of radiology. Line management structures were reviewed and the inspectors were satisfied that appropriate oversight measures were in place. The designated manager was also a member of the radiation safety committee (RSC).

Inspectors reviewed a sample of referrals and spoke with staff and management. From the evidence reviewed the inspectors were satisfied that only referrals for medical radiological procedures from those who were entitled to refer had been carried out. Similarly, only those entitled to act as a practitioner had taken clinical responsibility for medical exposures. Medical Mobile Diagnostics Ltd. was also found to have appropriate medical physics involvement in line with the level of radiological risk.

Inspectors also reviewed records and other documentation and communicated with staff and management to assess the safe delivery of medical exposures by Mobile Medical Diagnostics Ltd. Information relating to patient exposure was included on all of the reports of medical radiological procedures reviewed on the day of inspection. Written protocols were available for standard medical radiological procedures and diagnostic reference levels (DRLs) were found to have been established for medical radiological procedures and were available for use by radiographers on the mobile X-ray equipment inspected on the day of inspection.

All referrals reviewed as part of the inspection were in writing and accompanied by sufficient information. Staff working at the Mobile Medical Diagnostics Ltd. informed the inspectors that a practitioner justified all medical exposures in advance and a record of justification in advance by a practitioner was found on all records reviewed on the day of inspection.

In addition, arrangements were found to be in place regarding recording incidents involving, or potentially involving accidental and unintended exposures to ionising radiation. However, while Mobile Medical Diagnostics Ltd. was found to be compliant with the requirements of Regulation 17, as an area for improvement, efforts should

be taken by management to ensure that staff are aware of the importance of reporting potential incidents so that these are available for analysis and trending.

The inspectors reviewed documentation and records relating to the X-ray equipment and was assured that it was kept under strict surveillance with regards to radiation protection. A quality assurance (QA) programme, which included regular performance testing, had been established and was found to be maintained. An up-to-date inventory was provided in advance of the inspection.

Overall on the day of inspection, inspectors found a high level of compliance at Mobile Medical Diagnostics Ltd. with the regulations assessed during this inspection.

Regulation 4: Referrers

The inspectors reviewed a sample of referrals and the referral policy for medical exposures that had been carried out and spoke with staff, including radiographers working at Medical Mobile Diagnostics Ltd. Staff and management described the process where staff checked that referrers were an Irish Medical Council registered doctor or an advanced nurse practitioner approved by the RSC as a referrer for Medical Mobile Diagnostics Ltd. The inspectors found that referrals were only accepted at Mobile Medical Diagnostics Ltd. from those entitled to refer in line with Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

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

Judgment: Compliant

Regulation 6: Undertaking

The inspectors spoke with staff and management working at Mobile Medical Diagnostics Ltd. and reviewed documentation and other records, to ensure that appropriate governance and management arrangements were in place for the safe delivery of medical exposures.

A RSC was in place to provide governance for the radiation protection of service users. Membership of the RSC included the chairperson who was a consultant radiologist and clinical director, medical physicist, the chief executive officer (CEO), radiation safety officer, director of radiology, and deputy radiography services manager (RSM). The RSC reported to the CEO who was a member of the board of directors. Line management structures were also in place which provided day-to-day oversight of medial exposures conducted by staff at Medical Mobile Diagnostics Ltd.

The designated manager was the director of radiology who reported directly to the CEO. The deputy RSM reported directly to the director of radiology and was the line manager of the radiography staff and lead operations coordinator. The clinical director was a consultant radiologist who provided oversight for the delivery of services with two other clinical advisers.

Overall, inspectors were satisfied that there was a clear allocation of responsibility to individuals, as defined in the regulations, and that governance and management arrangements were in place to ensure the safe delivery of medical radiological procedures.

Judgment: Compliant

Regulation 8: Justification of medical exposures

A sample of referrals were reviewed by 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. On the day of inspection, radiographers who were the practitioners with responsibility for justification explained to inspectors the process of how medical exposures were justified in advance and how this justification was recorded in two places. A record of justification in advance by a practitioner was found to be in line with this process in the sample of referrals reviewed by inspectors.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and a medical physicist were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. The practical aspects of medical radiological

procedures conducted by Mobile Medical Diagnostics Ltd. were also found to be only carried out by radiographers.

Judgment: 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 Mobile Medical Diagnostics Ltd. Inspectors also observed DRLs were available for use on X-ray equipment on-site on the day of inspection. The inspectors also found evidence that where a local facility DRL was found to exceed the national DRL, this was investigated by staff and corrective measures implemented as required by the regulations.

Judgment: Compliant

Regulation 13: Procedures

Inspectors reviewed a sample of medical radiological procedures and found that information relating to patient exposure formed part of the report of these medical radiological procedures as required by Regulation 13(2). The inspectors also found that written protocols were established for standard medical radiological procedures on the X-ray equipment.

Inspectors reviewed documentation and a sample of clinical audits carried out at the facility related to medical exposure. Inspectors found evidence that a clinical audit strategy was available for review on the day of inspection and although the strategy had been reviewed in June 2024, it did not align with HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* published in November 2023. For example, inspectors found that some of the essential elements, including resources, tools and focus, were not fully documented and therefore the clinical audit strategy document needs to be further reviewed to ensure all essential elements are aligned with the requirements of this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

An up-to-date inventory of all medical radiological equipment was also provided as part of the inspection. Inspectors were satisfied that an appropriate QA programme had been established, which reflected the nature of the X-ray services provided, to ensure that medical radiological equipment was kept under strict surveillance. The inspectors noted that recently acquired X-ray equipment had acceptance testing completed by a medical physicist before first clinical use, as required by the regulations. Inspectors also noted that regular dose audits were completed by the radiation safety officer and reviewed at the RSC.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Mobile Medical Diagnostics Ltd. was found to have a system in place to facilitate the reporting and recording of actual or potential accidental or unintentional exposures. While inspectors found that Mobile Medical Diagnostics Ltd were compliant with the requirements of the regulations on the day of inspection, management should increase awareness and encourage a stronger reporting culture to assure themselves that all incidents, especially potential accidental and unintended exposures, are captured and reported by staff.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The inspectors were satisfied from communicating with staff, and a review of documentation, that adequate processes were in place to ensure the continuity of medical physics expertise at the facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The inspectors reviewed documentation and spoke with staff at the hospital, including a medical physicist, and were satisfied that arrangements were in place to ensure that the involvement and contribution of a medical physicist was in line with the requirements of Regulation 20. An example of good practice was found regarding the involvement of medical physics in the definition of the QA programme

for the medical radiological equipment which considered the mobile nature of the X-ray service provided.

Judgment: 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 a medical physicist was appropriately involved at the Mobile Medical Diagnostics Ltd. in line with the radiological risk.

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, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Summary of findings	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Compliant
Regulation 8: Justification of medical exposures	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant

Compliance Plan for Mobile Medical Diagnostics Ltd. OSV-0005948

Inspection ID: MON-0042300

Date of inspection: 25/06/2024

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 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
MMD will review and update their Clinical Audit Strategy to comply with the regulation 13: Procedures
I intend to separate the QA and Clinical Audit Strategy to clarify compliance with the standards and will utilise the template provided by Hiqa.

1. Oversight
– MMD will outline who has responsibility for clinical audit. We will confirm which committee has oversight with the undertaking and that the strategy is approved by the appropriate committee.

2. Communication
We will include what communication channels that are in place to include all relevant staff in the audits and outline how communication takes place for learning.
The strategy will identify how all stakeholders have been informed of the clinical audit strategy.

3. Resources
We will outline how clinical audit is supported in the organisation from a resource perspective, how we incorporate it into daily practice and how we allocate time for staff.
The strategy will also include:
• a clinical audit training plan and which include training tools and available techniques for staff.
• who the clinical audit lead is and who the suitably qualified staff in post are to support clinical audit.
• how resources are allocated to incorporate clinical audit into daily practice and the mechanisms in place to manage the time implications (knock on effect on services)

4. Focus
The strategy will also outline:
• how the undertaking has ensured that clinical audit is prioritised based on risk and

service needs to improve the quality and outcome of patient care.
• how we incorporate clinical audit into daily practice and has mechanisms in place to manage the time implications (knock on effect on services)
• clinical audit training is available to all staff to include training on tools and available techniques.

5. Tools The strategy will outline tools and techniques used for audit

6. Focus – It will outline how the undertaking has given staff and tools, audit technique training and time for clinical audits to be carried out.

7. Coverage and Action: the scope and depth of the clinical audit strategy will be included to ensure audits are appropriate in depth and partial audits are included as deemed necessary. Action plans will be part of the audit strategy when results require learning and improvements. This will feed into the appropriate committee.

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 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	15/09/2024