Health Information and Quality Authority

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

<table>
<thead>
<tr>
<th>Name of Medical Radiological Installation:</th>
<th>Midland Regional Hospital Portlaoise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undertaking Name:</td>
<td>Health Service Executive</td>
</tr>
<tr>
<td>Address of Ionising Radiation Installation:</td>
<td>Block Road, Ballyroan, Portlaoise, Laois</td>
</tr>
<tr>
<td>Type of inspection:</td>
<td>Announced</td>
</tr>
<tr>
<td>Date of inspection:</td>
<td>21 January 2020</td>
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<tr>
<td>Medical Radiological Installation Service ID:</td>
<td>OSV-0007364</td>
</tr>
<tr>
<td>Fieldwork ID:</td>
<td>MON-0028236</td>
</tr>
</tbody>
</table>
The Midland Regional Hospital Portlaoise (MRHP) is a statutory hospital, owned and managed by the Health Service Executive (HSE). The radiology department in MRHP provides services for adult and paediatric inpatients and outpatients in the locality and in the region. It also supports adult and paediatric emergency departments, theatre and intensive care units. Imaging services include general radiography, ultrasound, computed tomography (CT) and fluoroscopy. Approximately 48,000 procedures are conducted annually within the department and of this number, 32,000 relate to general radiography. The number of procedures conducted in the CT room is 8,000 and 350 procedures involve fluoroscopy and interventional radiography. The radiology department staff includes consultant radiologists, radiographers, nursing staff, clerical staff and multitask attendants.
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 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 and management 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 complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

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\(^1\) 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.
This section describes HIQA’s findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:
This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

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:

<table>
<thead>
<tr>
<th>Date</th>
<th>Times of Inspection</th>
<th>Inspector</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuesday 21 January 2020</td>
<td>09:00hrs to 17:00hrs</td>
<td>Agnella Craig</td>
<td>Lead</td>
</tr>
<tr>
<td>Tuesday 21 January 2020</td>
<td>09:00hrs to 17:00hrs</td>
<td>Noelle Neville</td>
<td>Support</td>
</tr>
</tbody>
</table>
Governance and management arrangements for medical exposures

Inspectors were assured of the quality and safe conduct of the medical exposures in this facility which was evidenced in the information gathered during inspection. Inspectors were assured by the governance and management structures in place in the Midland Regional Hospital Portlaoise (MRHP) as a clear allocation of responsibilities was identified to inspectors. Staff who met with inspectors had a good awareness of these responsibilities.

The general manager (or their nominee) is a member of the Radiation Safety Committee (RSC) and the specific reporting pathway for this committee was detailed to inspectors. The pathway for informing the Health Service Executive of incidents was also documented. Implementation of the work of the RSC was through the relevant heads of departments.

From the documentation and records reviewed by inspectors and the discussions with staff, inspectors were assured by the systems and processes in place that referrals were only accepted from those entitled to act as referrers, as identified in Regulation 4.

Radiologists and radiographers were practitioners in this facility and their specific roles for each type of procedure was identified in documentation and communicated by staff. Radiographers and radiologists performed the practical aspects of medical exposures with one exception, where an individual is listed as being delegated the practical aspects. However, inspectors were informed that all procedures take place in the presence of either a radiologist or radiographer.

The specific role and responsibilities of the medical physics expert (MPE) were identified to inspectors and listed in the service level agreement (SLA) provided to inspectors for review. The SLA assured inspectors of the continuity of services and provides a good example of how resources can be shared across facilities within the same hospital grouping. Inspectors were also assured by the documentation reviewed and their communications with staff that the level of involvement of the MPE was in line with the level of radiological risk posed in this facility.

Regulation 4: Referrers

The policy document *Making and accepting referrals for medical exposures* which was reviewed in advance of inspection, identified the referral process in place in the Midland Regional Hospital Portlaoise (MRHP). Referrals at this hospital are received both in electronic and hard copy format from sources both internal and external to the hospital.
Inspectors were informed that referrals received in hard copy format are typically from local general practitioners (GPs) and these referrals are checked to ensure they include a Medical Council number before being accepted. Electronic referrals could only be made by users with appropriate ordering rights on the hospital’s Radiology Information System (RIS).

The list of advanced nurse practitioners who can act as referrers was available in the radiology department and was also held by the radiology services manager. A discrepancy was noted in the list available in soft copy and the hard copy version available in the clinical area. The importance of making sure that hard copy information is kept up-to-date was discussed with staff and staff clarified that the soft copy version was in the process of being verified before becoming available in the clinical areas.

Staff that spoke with inspectors demonstrated a comprehensive understanding of the referral process and this was consistent with local policy. Referrals for medical radiological procedures, reviewed on the day of inspection, were only accepted from those entitled to refer as per Regulation 4.

Judgment: Compliant

**Regulation 5: Practitioners**

Documentation reviewed by inspectors identified that radiographers and radiologists act as practitioners in this hospital, with the specific role of the radiographer in accepting clinical responsibility for plain film X-ray outlined in this document. The radiologist was identified as having clinical responsibility for CT and fluoroscopy, with the exception of brain CT scans, which the clinical specialist radiographer can justify. The list of who can act as practitioners was available in the radiology department and was also held by the radiology services manager. On the day of inspection, inspectors reviewed a sample of records in relation to medical exposures and found that only those entitled to act as practitioners, as per the regulations, had taken clinical responsibility for individual medical exposures.

Judgment: Compliant

**Regulation 6: Undertaking**

The hospital had a clear allocation of responsibilities for the radiation protection of service users undergoing medical exposure to ionising radiation. Staff were able to communicate the lines of governance and clinical oversight to inspectors during the inspection. The documentation provided in advance of the inspection detailed the structures in place at a local, hospital, and up to HSE board level. An extract from
the local rules provided to inspectors detailed the terms of reference of the Radiation Safety Committee. This document was noted to be out of date as it referenced older legislation; however, inspectors were informed that it is in the process of being updated.

Judgment: Compliant

**Regulation 10: Responsibilities**

Inspectors were assured by the systems and processes in place in the hospital that all medical exposures took place under the clinical responsibility of a practitioner. Only those recognised as practitioners conducted medical exposures at the hospital with the exception of one individual who was delegated the practical aspects. However inspectors were informed that a radiographer or radiologist was present for all procedures including those carried out by the listed individual. Inspectors noted that the practitioner and medical physics expert (MPE) were involved in the optimisation process and the referrer and practitioner were involved in the justification process.

Judgment: Compliant

**Regulation 19: Recognition of medical physics experts**

Inspectors were informed that the MPE was available on site one day per week and provided cover remotely one additional day per week. A service level agreement (SLA) between this hospital and a large teaching hospital in the same hospital group was in place for the provision of medical physics expertise and this assured the undertaking of the continuity of services provided at this facility. This SLA is a good example of how facilities can share resources and learning across hospitals within the same hospital group.

Judgment: Compliant

**Regulation 20: Responsibilities of medical physics experts**

From the documentation reviewed prior to and on the day of inspection and from speaking with staff in the hospital, it was clear that the MPE was involved in activities identified in Regulation 20. The service level agreement reviewed by the inspectors listed the role and responsibilities specifically of the MPE, as distinct from the Radiation Protection Advisor (RPA). These responsibilities were as identified in
the regulations and included taking responsibility for dosimetry, carrying out quality assurance and acceptance testing of equipment, providing education sessions for staff, and involvement in the review of incidents and near misses as required. The MPE was a member of the Radiation Safety Committee.

Judgment: Compliant

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

From the information gathered in relation to this facility, inspectors were assured that the level of involvement of the medical physicist expert (MPE) was in line with the radiological risk posed by the service, and that the MPE was available for consultation and advice on matters relating to radiation protection of service users.

Judgment: Compliant

**Safe Delivery of Medical Exposures**

Inspectors found evidence that this hospital had appropriate systems and processes in place to ensure that effective and safe medical exposures are provided to service users. This included evidence of the use of diagnostic reference levels, written protocols for each type of procedure carried out and posters relating to pregnancy and the risks associated with radiation exposure available in the Radiology Department. An up-to-date inventory and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place. The specific process for reporting incidents and near misses in place in this facility detailed the roles and responsibilities of staff and the system of reporting incidents to the undertaking.

Although the documentation reviewed identified the personnel with specific responsibility for justification, which was in line with the regulations, a record that justification had been conducted was not evident in all records reviewed. Identifying a specific process to ensure documented evidence of justification for all procedures will facilitate the undertaking to come into compliance with Regulation 8(8) and 8(15).

Inspectors also found that this facility was not in compliance with Regulation 13(2) as information relating to patient exposure was not included on the report of the medical exposure.

Notwithstanding the two regulations which were found to be substantially compliant, overall, inspectors were assured by the arrangements in place that this service was
providing safe medical exposures to ionising radiation.

**Regulation 8: Justification of medical exposures**

All referrals reviewed by inspectors on the day of the inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff informed inspectors of the process they follow to obtain previous medical information, where practical.

Inspectors reviewed the hospital’s policy on *Making and accepting referrals for medical exposure* which defined who can refer as per the regulation and also outlined the processes to be followed by staff when accepting a referral for medical exposure to ionising radiation. This document identified the personnel with clinical responsibility for specific processes; this included the radiographer with responsibility for accepting and justifying plain X-rays and the radiologists holding responsibility for accepting and justifying CTs and fluoroscopy procedures with the exception of CT brain referrals. These may be justified by a Clinical Specialist Radiographer.

Information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure. Staff informed inspectors that they could access information relating to the dose level associated with a procedure should a patient ask about this and radiographers provided information on risk and benefit to patients and carers and comforters.

Although practitioners informed inspectors that justification in advance is conducted for all referrals, inspectors were informed that a record of justification is not documented for all procedures. In particular, a record of justification of general X-ray is not formally documented. However, staff informed inspectors that sign off on the triple identification check indicates that the procedure is justified. This was not explicit in any of the documentation reviewed by inspector.

To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that records evidencing that justification in advance has taken place are available for all procedures involving medical exposure to ionising radiation.

**Judgment:** Substantially Compliant

**Regulation 11: Diagnostic reference levels**

Details of the process for establishing and reviewing diagnostic reference levels (DRLs) were reviewed by inspectors in the document *Guidelines for DRL’s of Medical Exposures Standard Operating Procedure*. Inspectors were also informed by staff that DRLs for radiodiagnostic examinations were established, reviewed and
compared to national DRLs. DRLs relevant to the medical exposures carried out in this facility were displayed in the Radiology Department and staff demonstrated an awareness of the availability and use of DRLs.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for the standard procedures carried out in this department were available in both hard and soft copy and staff in the clinical areas showed inspectors how to access these. Inspectors were informed that iRefer guidelines were available on desktops in the department and on the HSE intranet and staff in the clinical areas demonstrated how these can be accessed.

A list of clinical audits carried out in 2019 was provided to inspectors. Triple identification checks and pregnancy status were routinely audited in this facility and inspectors were informed that the audit plan for 2020 was currently being devised. However, inspectors were informed that implementing this plan was reliant on having adequate staffing in place to carry out audits and enact subsequent quality improvement plans as required.

Inspectors observed that information relating to patient exposure is not routinely recorded on the patient’s report. Staff confirmed this to inspectors on the day of inspection. In order for the undertaking to become compliant with Regulation 13(2), a system to record information relating to patient exposure needs to be included in the patient report.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of equipment. Inspectors were informed that the replacement of the CT scanner has been listed on the risk register. Inspectors noted in the minutes of the Radiation Safety Committee meetings that the CT scanner, although passed its nominal replacement date, was approved for clinical use and had passed all necessary quality assurance testing.

Inspectors were satisfied that appropriate quality assurance and quality control programmes were in place and that the role of the MPE in relation to equipment was evident from the records reviewed.
Judgment: Compliant

**Regulation 16: Special protection during pregnancy and breastfeeding**

Inspectors reviewed the hospital’s recently approved policy on *The protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures*. This policy outlined the procedures to be followed when women of childbearing age are referred and present to the hospital for procedures involving the use of ionising radiation. The specific roles and responsibilities of staff were outlined in this document and staff demonstrated a knowledge and understanding of this policy.

Posters alerting patients to inform staff of their pregnancy status were on display in the waiting areas of the Radiology Department. The information on these posters was displayed in multiple languages.

Judgment: Compliant

**Regulation 17: Accidental and unintended exposures and significant events**

Reasonable measures were in place in this facility to minimise the risk of accidental or unintended exposures to service users. The recently approved *Guideline for incident/near miss reporting* reviewed by inspectors identified staff roles, responsibilities and the processes associated with managing incidents and near misses. Staff informed inspectors of the process and this was in line with the document reviewed. The document also included details of how incidents should be reported to the undertaking through the National Radiation Protection Office of the Health Service Executive.

Inspectors were informed that all incidents are discussed at the Radiation Safety Committee (RSC) meetings. On review of the minutes of the RSC meeting, it was noted that one incident had not been discussed and inspectors were informed that this had been missed due to staffing change over. To prevent a similar issue reoccurring, the process of filling in a hard copy form for the Quality and Safety Manager and sending a photocopy of this to the Radiology Services Manager (RSM) may benefit from an evaluation of efficiency and effectiveness.

Inspectors were informed that all incidents are also discussed at the Radiology Governance meetings and the Radiographer Staff meetings. Review of incidents was noted as an agenda item at the Radiology Quality and Safety Specialty Committee meetings and inspectors noted that incidents involving ionising radiation were reported in the minutes of this committee’s meetings.
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:

<table>
<thead>
<tr>
<th>Regulation Title</th>
<th>Judgment</th>
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</thead>
<tbody>
<tr>
<td>Governance and management arrangements for medical exposures</td>
<td></td>
</tr>
<tr>
<td>Regulation 4: Referrers</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 5: Practitioners</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 6: Undertaking</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 10: Responsibilities</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 19: Recognition of medical physics experts</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 20: Responsibilities of medical physics experts</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 21: Involvement of medical physics experts in medical radiological practices</td>
<td>Compliant</td>
</tr>
<tr>
<td>Safe Delivery of Medical Exposures</td>
<td></td>
</tr>
<tr>
<td>Regulation 8: Justification of medical exposures</td>
<td>Substantially Compliant</td>
</tr>
<tr>
<td>Regulation 11: Diagnostic reference levels</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 13: Procedures</td>
<td>Substantially Compliant</td>
</tr>
<tr>
<td>Regulation 14: Equipment</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 16: Special protection during pregnancy and breastfeeding</td>
<td>Compliant</td>
</tr>
<tr>
<td>Regulation 17: Accidental and unintended exposures and significant events</td>
<td>Compliant</td>
</tr>
</tbody>
</table>
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. Specific 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:**

<table>
<thead>
<tr>
<th>Regulation Heading</th>
<th>Judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation 8: Justification of medical exposures</td>
<td>Substantially Compliant</td>
</tr>
<tr>
<td><strong>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</strong> Modifications required by National Nimis (Change Org) on &quot;arrival screen&quot; to facilitate vetting of &quot;Walk in&quot; patients to streamline the process. As an interim measure, the Radiology Department, Midland Regional Hospital, Portlaoise will record on the NIMIS RIS that the Radiographer has justified the examinations, by typing their initials and &quot;J&quot;. If particular examination is not justified, this will be cancelled and/or recorded on the NIMIS RIS.</td>
<td></td>
</tr>
<tr>
<td>Regulation 13: Procedures</td>
<td>Substantially Compliant</td>
</tr>
<tr>
<td><strong>Outline how you are going to come into compliance with Regulation 13: Procedures:</strong> Discussion required by National NIMIS team and Change org (mKession) to consider the linking and population of the dose report to the Radiology report.</td>
<td></td>
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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).

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Regulatory requirement</th>
<th>Judgment</th>
<th>Risk rating</th>
<th>Date to be complied with</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation 8(8)</td>
<td>An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.</td>
<td>Substantially Compliant</td>
<td>Yellow</td>
<td>01/04/2020</td>
</tr>
<tr>
<td>Regulation 8(15)</td>
<td>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.</td>
<td>Substantially Compliant</td>
<td>Yellow</td>
<td>01/04/2020</td>
</tr>
<tr>
<td>Regulation 13(2)</td>
<td>An undertaking shall ensure that information relating to patient exposure forms part of the report</td>
<td>Not Compliant</td>
<td></td>
<td>10/03/2020</td>
</tr>
</tbody>
</table>
of the medical radiological procedure.