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

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| Name of Medical Radiological Installation: | Mater Private South |
| Undertaking Name: | Mater Private Hospital |
| Address of Ionising Radiation Installation: | Building 11, Cherrywood Business Park, Bray Road, Loughlinstown, Co. Dublin |
| Type of inspection: | Announced |
| Date of inspection: | 23 July 2024 |
| Medical Radiological Installation Service ID: | OSV-0007844 |
| Fieldwork ID: | MON-0042844 |

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

Mater Private Network Cherrywood (Mater Private South) provides an outpatient diagnostic imaging service and has been in operation since 2020. The facility is located at Cherrywood Business Park, Building 11, Loughlinstown, Co. Dublin, D18 DH50. Services provided include MRI, x-ray, fluoroscopy and ultrasound imaging. The service operates 6 days a week.

The service falls under the governance of the Mater Private Network and is part of the wider diagnostic imaging department based at the main hospital in Eccles Street. Rapid access for advanced cardiac imaging service such as cardiac MRI is available. The diagnostic imaging department is part of the Mater Private Network at Cherrywood, where patients can avail of multiple appointments at one location in a single visit. Other services provided include specialist consultation, non-invasive cardiac testing,visa medicals and health check.

## 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 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] 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.

**1. Governance and management arrangements for medical exposures:**

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:**

| Date | Times of Inspection | Inspector | Role |
|---|---|---|---|
| Tuesday 23 July 2024 | 09:00hrs to 12:50hrs | Kay Sugrue | Lead |
| Tuesday 23 July 2024 | 09:00hrs to 12:50hrs | Emma O'Brien | Support |

## Governance and management arrangements for medical exposures

An inspection to assess compliance with the regulations at Mater Private South was completed on the 23 July 2024. During this inspection, inspectors visited the general radiography X-ray room and the fluoroscopy room in this facility.

Following discussions with staff and management and a review of documentation, inspectors found that the undertaking, the Mater Private Hospital, had ensured that there were appropriate governance and management arrangements in place to oversee the radiation protection of service users attending for medical exposures at this facility. It was evident that there was a direct reporting line from the designated manager of Mater Private South up to the undertaking.

Inspectors were satisfied that the appropriate people recognised under the regulations were allocated responsibility for referring for medical radiological procedures and for conducting the practical aspects for individual medical exposures. In addition, the undertaking had ensured there was appropriate involvement and contribution of a Medical Physics Expert (MPE) in line with the regulations and the radiological risk posed by the service.

However, some areas of improvement were identified by inspectors. For instance, documentation provided and viewed at the time of the inspection did not provide assurance that clinical evaluation of the outcome of fluoroscopy procedures was carried out by a practitioner in line with Regulation 10(1). In addition, from the evidence viewed and discussions with staff, inspectors were not satisfied that information relating to the dose delivered was included in the report of these procedures to ensure compliance with Regulation 13(2). In relation to Regulation 13(4), more action is needed by the undertaking to ensure that the allocation of responsibility for clinical audit practices at Mater Private South is clearly defined and clinical audit practices at this facility are implemented in line with the national procedures. Finally, inspectors noted that some of the local policies viewed as part of this inspection must be updated to fully align with the regulations.

Overall, despite the areas for improvement identified, inspectors found that staff at the Mater Private South demonstrated a commitment to the radiation protection of service users which was supported by clear and effective management structures for the radiological service provided at this facility.

## Regulation 4: Referrers

Inspectors reviewed a sample of referrals from both the fluoroscopy and general X-ray services and found that all referrals viewed were from individuals entitled to refer as per the regulations.

Judgment: Compliant

## Regulation 5: Practitioners

From the review of documentation and discussion with staff delivering medical exposures, inspectors were satisfied that only those entitled to act as a practitioner took clinical responsibility for medical exposures in line with this regulation.

Judgment: Compliant

## Regulation 6: Undertaking

Inspectors reviewed the governance, management and leadership arrangements in place at the Mater Private South including the allocation of responsibility for the radiation protection of service users to determine compliance with this regulation.

The designated manager for Mater Private South was the chief operations officer (COO) for the Mater Private Network facilities based in the Dublin area. A Radiation Safety Committee (RSC) was in place and had oversight of radiation protection of service users. This committee had multidisciplinary representation in attendance at each meeting. The RSC reported to the Quality Using Effective Safe Treatment (QUEST) Committee which in turn reported up to the Mater Private Hospital Group's Board. Minutes viewed from both these committees demonstrated that attendees included the designated manager and radiography services manager (RSM) from the Mater Private South and MPE representation. As the RSC met twice a year, there was a separate local management structure to ensure oversight of day-to-day operations of the radiology services at the Mater Private South. This included a direct line of communication from the radiography service manager to the designated manager and upwards to the undertaking representative and members of the Board of the Mater Private Hospital.

The evidence gathered from this inspection satisfied inspectors that the roles and responsibilities for the conduct of medical exposures and the radiation protection of service users were allocated to persons recognised as referrers and practitioners under the regulations. Continuity of medical physics expertise, contribution and involvement was evident in arrangements reviewed and discussions with medical physics staff.

While individuals allocated with responsibility met regulatory requirements as discussed above, not all aspects regarding the allocation of responsibility were met. For example, inspectors identified that the responsibilities for the clinical evaluation of the outcome of fluoroscopy procedures and clinical audit practices required improvement. Documentation provided by staff to inspectors and described by staff as the report of the fluoroscopy procedure did not show evidence that the clinical evaluation of the outcome of these procedures had been completed by a practitioner. In addition, information relating to the patient dose was not included in this documentation. In relation to clinical audit practices, inspectors found that responsibility for the oversight of clinical audit rested with the RSC, however, it was unclear to inspectors how individual responsibility for clinical audit was filtered down and assigned to staff working at the Mater Private South. Finally inspectors noted that some radiation protection documents needed to be revised to align with the regulations.

Inspectors concluded that overall, there were established and effective arrangements in place to oversee the radiation protection of service users at this facility, however, further action was needed by the undertaking to address the findings above, to ensure compliance with Regulation 6(3).

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

The evidence gathered during this inspection demonstrated that recognised referrers and practitioners were involved in the justification of individual medical exposures on the day of inspection. Similarly, inspectors were satisfied that there was practitioner and MPE involvement in the optimisation of medical exposures at the facility.

From discussions with staff and a review of records, inspectors found that the practical aspects of all medical exposures for general radiography and fluoroscopy procedures were carried out by individuals entitled to act as practitioners in the regulations. However, as described under Regulation 6, evidence of the clinical evaluation of the outcome for fluoroscopy procedures presented to inspectors did not provide sufficient assurance that this aspect of clinical responsibility was completed by a recognised practitioner. Inspectors found that the undertaking must take action to ensure that all aspects of clinical responsibility is allocated to a practitioner as per Regulation 10(1).

Judgment: Substantially Compliant

## Regulation 19: Recognition of medical physics experts

On the day of inspection, the inspector was satisfied that the undertaking for the Mater Private South had appropriate measures in place to ensure the continuity of medical physics expertise at this facility.

Judgment: Compliant

## Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificate of the MPE at Mater Private South and were satisfied that the MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). For example, there was evidence to show MPE involvement in the definition and performance of the quality assurance (QA) of medical radiological equipment. Inspectors noted that acceptance testing records for both units in use had been completed prior to the first clinical use by an MPE, as per the regulations. In addition, records of annual QA had been completed by the MPE in line with the QA programme. The evidence gathered satisfied inspectors that an MPE had taken responsibility for dosimetry, contributed to the optimisation of the radiation protection of patients and contributed to training on radiation protection matters for staff delivering medical exposures. Minutes viewed from RSC meetings held twice a year demonstrated an MPE was in attendance at each meeting held in 2023 and 2024.

Judgment: Compliant

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

Staff informed inspectors that an MPE was available to staff to address any radiation protection issues or queries that may arise. From the evidence gathered during this inspection, inspectors were satisfied that MPE involvement was appropriate and proportionate to the radiological risk associated with services provided at the Mater Private South.

Judgment: Compliant

## **Safe Delivery of Medical Exposures**

Following a review of documentation, medical radiological records and discussions with staff and management, inspectors were satisfied that there were effective processes and systems in place for the safe delivery of medical exposures at Mater Private South. Inspectors found the undertaking was compliant with Regulations 8,11,14,16 and 17, with improvements required to comply with Regulation 13.

Inspectors visited both the general radiography and fluoroscopy services and noted that notices presenting information relating to the risks and benefits associated with procedures provided at this facility were available to service users to view in waiting areas. Similarly, awareness regarding the special protections required during pregnancy was also presented in a similar way.

Good practices were evident in relation to the justification of medical radiological procedures. For example, records showed that there was a written referral by a recognised referrer for each medical radiological procedure which provided appropriate information and clinical data to inform justification in advance by a practitioner. The record of justification for each medical exposure was evident to inspectors and maintained on the radiology information system, thereby, demonstrating compliance with Regulation 8. Pregnancy enquiries were made by the practitioner in advance of each examination, documented and uploaded onto the same system demonstrating evidence of compliance with Regulation 16.

Inspectors were satisfied that facility diagnostic reference levels (DRLs) had been established, were available to apply in radiological practices and were all below national levels. In relation to Regulation 14, the evidence demonstrated that staff at this facility ensured that the strict surveillance of medical radiological equipment in use was maintained in line with the QA programme established by the MPE. There was also evidence to demonstrate there were appropriate systems in place for the identification, recording and management of radiation incidents and near misses by staff should an event occur.

Inspectors viewed written protocols for standard medical radiological procedures and also noted the availability of referral guidelines at the point of care. While complying with Regulations 13(1) and 13(3), more action was required to ensure that information relating to the patient radiation dose is included in the report of each medical radiological procedure in line with Regulation 13(2). Furthermore, from the evidence gathered, clinical audit practices at Mater Private South required improvement to ensure they are carried out in line with the principles and essential criteria outlined in the national procedures document.

Despite the documentary improvements required with respect of Regulations 13(2) and 13(4), inspectors found that staff and management at Mater Private South had systems in place to help ensure the radiation protection of service users and safe delivery of medical radiological procedures at this facility.

## Regulation 8: Justification of medical exposures

Inspectors visited both X-ray rooms and the patient waiting area and saw that information about medical radiological procedures delivered at this facility was provided in notices available for viewing by service users in all of these areas.

Records viewed during the inspection demonstrated that referrals were in writing and contained sufficient relevant patient details and clinical information to help inform the justification of each medical exposure requested by a practitioner. Justification in advance of each medical exposures was recorded by the practitioner carrying out the procedure on the radiology information system. Staff delivering medical exposures informed inspectors, that although an infrequent occurrence, incomplete referrals or referrals not deemed appropriate were rejected and the referrer informed. The evidence gathered demonstrated compliance with Regulations 8.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

Inspectors found that DRLS for standard medical exposures delivered at this facility had been established, compared with national DRLs and reviewed in line with this regulation. Facility DRLs with comparable national DRLs were available to staff in both areas visited.

Judgment: Compliant

## Regulation 13: Procedures

Inspectors reviewed written protocols for standard medical radiological procedures delivered in both general X-ray and the fluoroscopy services. Inspectors were informed that there was multidisciplinary input for the development of these protocols with a formal system of approval in place.

Referral guidelines were evident on desktop computers in the clinical area.

Information relating to patient exposure was included in all reports from medical exposures generated in general X-ray which accounted for the majority of examinations provided in this facility. However, this was not the case for fluoroscopy medical exposures. The reports provided to inspectors for these procedures did not include information relating to the patient exposure. Consequently, inspectors were not satisfied the requirements set out under Regulation 13(2) were consistently met for all medical radiological procedures delivered at the Mater Private South.

Staff at the Mater Private South facility had completed clinical audits in 2023 and 2024 and these were reviewed by inspectors in addition to local policies and

procedures to assess compliance with Regulation 13(4). Overall, inspectors noted that there was a limited number of audits completed within the last year which were all process audits. The RSC had oversight of clinical audit practices as was evident in minutes reviewed by inspectors. When clinical audit practices at this facility were assessed against the principles and essential criteria outlined in the national procedures, inspectors found improvements were required. For example, it was not clear to inspectors if actions and recommendations identified from the audits carried out were assigned to individuals responsible for implementing these actions within defined time lines. A clinical audit strategy, the comprehensive allocation of responsibility for clinical audit practices and associated resources including multidisciplinary input was not evident from a review of documentation and discussions with staff and management. Management informed inspectors that this gap in compliance had been identified and work was underway to ensure clinical audit practices at this facility aligned with the national procedures as required under Regulation 13(4).

Judgment: Not Compliant

## Regulation 14: Equipment

From discussions with staff and management and a review of documentation and records, inspectors found that all medical radiological equipment was kept under strict surveillance. Records viewed demonstrated that QA by an MPE and routine performance testing were implemented and maintained for each piece of medical radiological equipment at the Mater Private South. This included daily and monthly QA by radiographers. Inspectors were informed that a previous gap in internal QA had been addressed by training additional radiographers to perform QA to ensure that monthly QA frequencies are consistently met.

Overall, while meeting the requirements of this regulation, inspectors noted that the QA programme for this facility should be reviewed to include daily QA performed by radiographers which was evident at the time of the inspection.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were satisfied from documentation viewed and discussions with staff that a practitioner was responsible for determining the pregnancy status of relevant service users in advance of each medical radiological procedure. Records were uploaded under the patient record on the radiology information system and a sample of these records were viewed by inspectors. In addition, notices were evident in waiting areas to raise awareness of the special protection required during

pregnancy in advance of medical exposure to ionising radiation. The evidence viewed by inspectors demonstrated compliance with this regulation.

Judgment: Compliant

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

Mater Private South had a system in place to record and analyse potential or actual accidental unintended exposures. This included an electronic incident reporting system and a weekly incident meeting to disseminate information to staff working in the radiology department. Additional means of communication were described by staff to inspectors such as regular staff meetings, electronic messaging and email. Inspectors were informed that radiography staff work across three facilities in the Dublin area, therefore these means of communication are important to ensure appropriate information and learning from radiation incidents is shared among all staff involved in the delivery of medical exposures under the remit of this undertaking.

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 |
|---|---|
| **Governance and management arrangements for medical exposures** | |
| Regulation 4: Referrers | Compliant |
| Regulation 5: Practitioners | Compliant |
| Regulation 6: Undertaking | Substantially Compliant |
| Regulation 10: Responsibilities | Substantially 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 |
| **Safe Delivery of Medical Exposures** | |
| Regulation 8: Justification of medical exposures | Compliant |
| Regulation 11: Diagnostic reference levels | Compliant |
| Regulation 13: Procedures | Not Compliant |
| Regulation 14: Equipment | Compliant |
| Regulation 16: Special protection during pregnancy and breastfeeding | Compliant |
| Regulation 17: Accidental and unintended exposures and significant events | Compliant |

# Compliance Plan for Mater Private South OSV-0007844

## Inspection ID: MON-0042844

## Date of inspection: 23/07/2024

**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 6: Undertaking | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 6: Undertaking:
Allocation of responsibilities:
A policy will be developed outlining the allocation of responsibilities for each stage of the fluoroscopically guided procedure in relation to SI 256 (2018). Clinical evaluation of the outcome will be the responsibility of the performing clinician who will act as the practitioner. The radiographer will remain as practitioner for all other aspects of the exposure.
This change in practice and associated documentation will be presented for approval at the Radiation Safety Committee in December 2024.

Dose Documentation:
The electronic health record (EHR) will be modified to add dose information, as recorded in the system by the radiographer, to the clinicians report of the procedure. This report is documented as the surgeons operative note in the EHR, contains details on the procedure performed including the use of fluoroscopy for guidance and is electronically signed by the clinician.

Clinical Audit:
The Mater Private Network is currently in the process of implementing a Clinical Audit Strategy, Schedule and Report Template. This will address the allocation of responsibility for how clinical audit is assigned to staff working at Mater Private South.
A draft clinical audit strategy will be presented to the Radiation Safety Committee at the December 2024 meeting with a view to approving and implementing this strategy in January 2025. A clinical audit schedule will also be presented for approval.
A clinical audit template, based on HIQAs guidance has been designed and is now in use for all ongoing audits.

Revision of Radiation Protection Documentation:

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| The document highlighted on the day of inspection (Rad-Gen-30 – Pregnancy policy) is currently being revised and the error remediated. This will be completed & document controlled by the next Radiation Safety Committee meeting, December 2024. |

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| Regulation 10: Responsibilities | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 10: Responsibilities: Reg 10 (1)
A policy will be developed outlining the allocation of responsibilities for each stage of the fluoroscopically guided procedure in relation to SI 256 (2018). Clinical evaluation of the outcome will be the responsibility of the performing clinician who will act as the practitioner. The radiographer will remain as practitioner for all other aspects of the exposure.
This change in practice will be presented to the Radiation Safety Committee in December 2024 for approval.

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| Regulation 13: Procedures | Not Compliant |

Outline how you are going to come into compliance with Regulation 13: Procedures: Reg 13 (2)
The electronic health record (EHR) will be modified to add dose information, as recorded in the system by the radiographer, to the clinicians report of the procedure. This report is documented as the surgeons operative note in the EHR and contains details on the procedure performed including the use of fluoroscopy for guidance.

Reg 13 (4)
A draft clinical audit strategy is currently in development and will be presented to the Radiation Safety Committee at the December 2024 meeting with a view to approving and implementing this strategy and associated documentation in January 2025. A clinical audit schedule will also be drafted for approval.
A clinical audit template, based on HIQAs guidance has been designed and is now in use for all ongoing audits.

## 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 | 28/02/2025 |
| Regulation 10(1) | An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner. | Substantially Compliant | Yellow | 28/02/2025 |

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|---|---|---|---|---|
| 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 | 28/02/2025 |
| 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 | 31/01/2025 |