

Inspection Report

15 February 2024



Optimax Laser Eye Clinic

Type of service: Independent Hospital-Refractive Eye Lasers

Address: 7 Derryvolgie Avenue, Belfast, BT9 6FL

Telephone number: 028 9066 1118

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

Information on legislation and standards underpinning inspections can be found on our website <https://www.rqia.org.uk/>, [The Independent Health Care Regulations \(Northern Ireland\) 2005](#) and the [Minimum Care Standards for Independent Healthcare Establishments \(July 2014\)](#)

1.0 Service information

Applicant Organisation/Provider: Optimax Clinics Limited	Registered Manager: Mrs Fiona Quinn
Applicant Responsible Individual: Mr Russell Ambrose	Date registered: 12 August 2019
Person in charge at the time of inspection: Mrs Fiona Quinn	
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor	
Brief description of how the service operates: <p>Optimax Laser Eye Clinic was initially registered with the Regulation and Quality Improvement Authority (RQIA) on 30 March 2006 as an Independent Hospital (IH) with the following categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and private doctor (PD) categories of care.</p> <p>On 3 April 2024 a retrospective service application was received on behalf of a new entity, Optimax Clinics Limited, to register with RQIA as an Independent Hospital (IH) with the following categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and private doctor (PD) categories of care.</p> <p>Mr Russell Ambrose submitted an application to register with RQIA as the responsible individual of Optimax Clinics Limited.</p>	
Equipment available in the service:	
Laser equipment: Manufacturer: Schwind Model: Amaris Serial Number: S244 Laser Class: 4 Wavelength: 193 nm	
Laser equipment: Manufacturer: IntraLase Model: FS60	

Serial Number: S0506-40039
 Laser Class: 3B
 Wavelength: 1053 nm

Types of laser treatments provided:

Refractive eye surgery – Lasek, Lasik and Photorefractive Keratectomy

2.0 Inspection summary

This was an announced inspection, undertaken by three care inspectors on 15 February 2024 from 10.00 am to 4.00 pm.

RQIA's Laser Protection Advisor (LPA) accompanied the inspectors and reviewed the laser equipment and the laser safety arrangements. Their findings and recommendations are appended to this report.

The purpose of the inspection was to assess progress with areas for improvement identified during and since the last inspection and assess compliance with the legislation and minimum standards.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; laser safety; the management of the patients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the adherence to best practice guidance in relation to COVID-19; the management of clinical records; clinical and organisational governance; and effective communication between patients and staff.

Additional areas of good practice identified included maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

No immediate concerns were identified regarding the delivery of front line patient care.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection. This inspection was facilitated by Mrs Quinn, Registered Manager.

The information obtained is then considered before a determination is made on whether the clinic is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

4.0 What people told us about the service?

Clients were not present on the day of the inspection and client feedback was assessed by reviewing the most recent client satisfaction surveys completed by Optimax Laser Eye Clinic.

Posters were issued to Optimax Laser Eye Clinic by RQIA prior to the inspection inviting clients and staff to complete an electronic questionnaire.

Three clients submitted responses. Client responses indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All clients indicated that they were very satisfied with each of these areas of their care. One client commented on the reassuring and caring service provided.

Two staff submitted questionnaire responses. Staff responses indicated that they were very satisfied with each of these areas of their care. One staff member commented that the team were supportive of each other.

Two visiting professionals submitted questionnaire responses. One respondent indicated that they felt client care was safe, effective, that clients were treated with compassion, that the service was well led and that they were very satisfied with each of these areas of client care. The other respondent indicated dissatisfaction regarding the care provided however, the same respondent submitted positive written comments such as the clinic was well-led and staff were client focussed.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

The last inspection to Optimax Laser Eye Clinic was undertaken on 14 February 2023; no areas for improvement were identified.

5.2 Inspection outcome

5.2.1 How does this service ensure that staffing levels are safe to meet the needs of patients and staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of a consultant ophthalmologist, an optometrist, a registered nurse and laser technicians/surgical assistants. Mrs Quinn confirmed that these staff have specialist qualifications and are suitably skilled and experienced in refractive laser eye surgery patient care.

The clinic staff take part in ongoing training to update their knowledge and skills, relevant to their role. Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team. A review of documentation evidenced that a new staff member recently recruited had completed an induction programme.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A review of the records confirmed that all staff had undertaken training in keeping with RQIA training guidance with the exception of medicines management. RQIA provided advice to Mrs Quinn in this regard. Following the inspection RQIA received email correspondence from Mrs Quinn confirming that medicines management training is currently being revised to include all areas as advised. Mrs Quinn gave us assurances that all relevant staff will undertake medicines management training once this revised format has been released by the training department.

Discussion with Mrs Quinn and review of documentation identified that arrangements were in place to check the registration status of all clinical staff on appointment and on an ongoing basis; to monitor staff professional indemnity and any practicing privileges agreements. These matters are discussed further in section 5.2.9.

Staff spoke positively regarding the clinic and their working relationships, they felt valued as members of the team and supported by management.

It was determined that appropriate staffing levels were in place to meet the needs of patients and that arrangements are being further developed to ensure all staff are suitably trained to carry out their duties.

5.2.2 How does the service ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Optimax Clinics Limited has a corporate human resources (HR) shared services department. The corporate HR department supports the registered manager during the recruitment process. The HR department is responsible for developing job descriptions, induction templates and employment contracts bespoke to roles and responsibilities; and issuing reference requests.

The registered manager is responsible for ensuring all recruitment records have been sought and uploaded to the electronic HR system. Discussions confirmed Mrs Quinn had a clear understanding of recruitment and selection legislation and best practice guidance.

The staff register reviewed was found to include the names and details of staff in keeping with legislation. It was noted that one new staff member had been appointed since the previous RQIA inspection.

A review of the new staff member's personnel file evidenced that all recruitment documentation, as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, had been sought and retained for inspection.

During a review of laser safety records, it became apparent that a staff member from a sister clinic located in Glasgow had worked for a brief period of time in Optimax Laser Eye Clinic in Belfast. Mrs Quinn informed us that the identified staff member has been employed by Optimax Clinics Limited for some time and their recruitment had been confirmed by the HR department. Mrs Quinn was advised that an AccessNI enhanced disclosure check should be completed for any staff member prior to working in Optimax Laser Eye Clinic in Belfast. In addition, the staff member's details should be included in the staff register and staff duty rota for Optimax Laser Eye Clinic. Mrs Quinn was very receptive to this advice and provided assurance that this matter would be addressed as a priority.

It was determined that recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance.

5.2.3 How does the service ensure that it is equipped to manage a safeguarding issue should it arise?

Mrs Quinn confirmed that treatments are not provided to persons under the age of 18 years.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Mrs Quinn confirmed that staff were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

The safeguarding champion named in the clinic policy had completed safeguarding training at the level required in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards. It was confirmed that a copy of the regional guidance document entitled [Adult Safeguarding Prevention and Protection in Partnership \(July 2015\)](#) was available for reference.

Appropriate arrangements were in place to manage a safeguarding issue should it arise.

5.2.4 How does the service ensure that medical emergency procedures are safe?

The arrangements in respect of the management of medical emergencies were reviewed.

Review of the medicines management policy found that it accurately reflected the arrangements in place to manage a medical emergency, with the exception of staff training requirements. This was discussed with Mrs Quinn who was receptive to this advice and provided assurances the policy would be amended in this regard. Protocols were also available to guide the team on how to manage recognised medical emergencies.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

Review of the emergency trolley found that systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available.

Staff spoken with were able to describe the actions they would take, in the event of a medical emergency, and were familiar with the location of medical emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency should one arise.

5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?

The arrangements for IPC procedures throughout the clinic were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

A tour of the premises was undertaken and the clinic was found to be clean, tidy and uncluttered. Cleaning schedules were in place and cleaning records were completed and up to date. Mrs Quinn discussed the procedure to decontaminate the environment and equipment between patients and this was in keeping with best practice.

A review of training records confirmed that staff had received IPC training commensurate with their roles and responsibilities. Staff spoken with on inspection demonstrated good knowledge and understanding of IPC procedures.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance and according to the treatments provided. The laser suite provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

Mrs Quinn and the IPC lead nurse confirmed only single use equipment is used for refractive laser treatments. There are contracts in place for disposal of sharps, clinical waste and pharmaceutical waste.

It was evidenced that a robust programme of IPC auditing is in place including an unannounced audit by the IPC expert advisor for Optilase. Audit compliance rates were found to be high. Mrs Quinn confirmed audit results are shared across all Optilase clinics for learning and development purposes. The findings from incidents relating to IPC matters are also shared and learning is disseminated across all Optilase Clinics. Mrs Quinn told us that regular inter-clinic IPC meetings take place.

The service had appropriate arrangements in place in relation to IPC and decontamination.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

It was evidenced through review of key documentation and discussion with Mrs Quinn that arrangements were in place at Optimax Laser Eye Clinic to minimise the transmission of COVID-19.

We confirmed that mitigating actions were documented and implemented as necessary to continue to keep risk of infection and transmission to a minimum in clinical areas and throughout the patient pathway.

The management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard

5.2.7 How does the service ensure that laser procedures are safe?

The arrangements in respect of the safe use of the laser equipment were reviewed.

The service has one laser suite and a number of consultation and treatment rooms. It was confirmed that refractive laser eye procedures are only carried out by a consultant ophthalmologist acting as the clinical authorised operator assisted by laser technicians acting as non-clinical authorised operators.

A review of the laser safety files found that they contained all of the relevant information required with regards to the laser equipment in use. There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the clinic and the LPA had been reviewed and was in date.

The clinic's LPA had completed a risk assessment of the premises during March 2021; no recommendations were made. Mrs Quinn advised that the clinic's LPA was scheduled to complete an onsite visit during March 2024, during which time an updated risk assessment would be undertaken.

Mrs Quinn confirmed that laser eye surgical procedures are undertaken by the consultant ophthalmologist in accordance with medical treatment protocols produced by the medical directors of Optimax Laser Eye Clinic. Systems were in place to review the medical treatment protocols on an annual basis.

A register of clinical and non-clinical authorised operators for the lasers was maintained however it did not include the name of a non-clinical authorised operator who as previously discussed, provided clinical cover at Optimax Belfast during June 2023.

This matter was discussed with Mrs Quinn who confirmed that moving forward the names of all clinical and non clinical operators working at the clinic would be reflected in the list of authorised operators.

As mentioned previously, a visit was undertaken by the LPA during March 2024. A copy of the updated local rules dated 1 March 2024 was shared with RQIA following inspection. These contained all relevant information pertaining to the laser equipment being used, an up to date register of authorised operators and addressed the recommendations made by RQIA's Laser Protection Advisor (LPA), which are appended to this report.

Review of the local rules confirmed that all required information was included:

- the potential hazards associated with lasers
- controlled and safe access
- authorised operators' responsibilities
- methods of safe working
- safety checks
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

Mrs Quinn confirmed that the LPS is aware that when the laser equipment is in use, the safety of all persons in the controlled area is their responsibility. Arrangements were in place for an authorised operator to deputise for the LPS, when required, who is suitably skilled to fulfil the role.

As previously discussed a review of training records confirmed that all clinical authorised operators had up to date training in keeping with the RQIA training guidance. It was confirmed that a recently recruited non-clinical authorised operator is due to undertake training in core of knowledge during March 2024.

Mrs Quinn confirmed that the laser surgical register is maintained every time the lasers are operated to include:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure given
- any accidents or adverse incidents

A review of the laser surgical register found it to be comprehensively completed.

The laser suite where the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. Mrs Quinn confirmed that both sets of doors to the laser suite are locked when the laser equipment is in use and can be opened from the outside in the event of an emergency.

The lasers are operated using keys that unauthorised staff do not have access to and there were arrangements in place in relation to the safe custody of the keys for the laser equipment.

Protective eyewear is available for laser assistants when required and for purposes of equipment maintenance.

The laser safety warning signs are displayed and also illuminated outside of the laser suite when the laser is in use and the illuminated light is turned off when the laser is not in use, as described within the local rules.

Arrangements have been established for the laser equipment to be serviced and maintained in line with the manufacturers' guidance. The most recent service reports reviewed were dated 5 April 2023.

Carbon dioxide (CO₂) fire extinguishers suitable for electrical fires were available in the clinic and arrangements were in place to ensure the fire extinguishers are serviced in keeping with manufacturer's instruction.

The fire risk assessment had been reviewed during February 2024.

It was determined that appropriate arrangements were in place to safely operate the laser equipment.

5.2.8 How does the clinic ensure patients have a planned programme of care and have sufficient information to consent to treatment?

Staff confirmed that all patients have a clinical evaluation with an optometrist who provides information and discusses treatment options.

During this initial consultation, patients are asked to complete a health questionnaire. Systems were in place to contact the patient's general practitioner (GP), with their consent, for further information if necessary.

The clinic has a list of fees available for each type of surgical procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

In accordance with General Medical Council (GMC) and the Royal College of Ophthalmologists guidance, patients have a consultation with their surgeon on a separate day in advance of surgery to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery for purposes of medical review and to complete the consent process for surgery.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment. Patients are also provided with clear post-operative instructions along with contact details if they experience any concerns. Systems were in place to refer patients directly to the consultant ophthalmologist or optometrist if necessary.

Staff informed us that systems were in place to review the patient following surgery at regular intervals if necessary.

Two patient care records reviewed were found to be well documented, contemporaneous and clearly outlined the patient journey.

The clinic has recently introduced an electronic care record (ECR) and consent procedure. The management of paper and electronic records within the clinic was found to be in line with legislation and best practice.

It was determined that appropriate arrangements were in place to ensure patients have a planned programme of care and have sufficient information to consent to treatment.

5.2.9 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within Optimax Laser Eye Clinic. Mr Russell Ambrose is the applicant responsible individual for the clinic and Mrs Quinn is the registered manager who is in day to day charge of the clinic.

Where the business entity operating a refractive eye service is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the registered provider, or person acting on their behalf, must be undertaken and documented every six months; as required by Regulation 26 of the Independent Health Care Regulations (Northern Ireland) 2005. The most recent unannounced monitoring visit was undertaken on 2 February 2024. A report of the visit was produced and made available for patients, their representatives, staff, RQIA and any other interested parties to read and an action plan developed to address any issues identified during the visit which included timescales and person responsible for completing the action.

Optimax Laser Eye Clinic has a Medical Advisory Board (MAB) that includes Mr Ambrose along with the chief executive officer, senior medical staff and directors of the organisation. The MAB meets quarterly and this meeting is also attended by other members of the senior management team.

Discussion with staff and a review of records evidenced that staff meetings take place every month and minutes were available to review.

Staff working in different roles within the clinic stated that there were good working relationships and that management were responsive to any suggestions or concerns raised.

Clinical governance

As discussed the clinical team includes a consultant ophthalmologist, an optometrist, a registered nurse and laser technicians/surgical assistants who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

The consultant ophthalmologist is considered to be a wholly private doctor as they are not affiliated with the Health and Social Care (HSC) sector in Northern Ireland (NI) and are not on the General Practitioner's (GP's) performer list in NI. Review of the consultant ophthalmologists' details confirmed evidence of the following:

- confirmation of identity
- current GMC registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained Medical Appraiser
- an appointed responsible officer (RO)
- arrangements for revalidation

As previously discussed the consultant ophthalmologist, who is a clinical authorised operator, has completed training in accordance with RQIA's training and is aware of their responsibilities under GMC Good Medical Practice.

All medical practitioners working within the clinic must have a designated RO. In accordance with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. Experienced senior doctors (called RO's) work with the GMC to make sure doctors are reviewing their work. As part of the revalidation process RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work.

The consultant ophthalmologist working within the clinic has a designated external RO due to their prescribed connection with other health care organisations.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the clinic.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place.

A review of practising privileges records confirmed that all required documents were in place. It was confirmed that the private doctor's practising privileges agreement is updated every two years.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of robust medical governance arrangements within the organisation.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals.

The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed to address any shortfalls identified during the audit process.

A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

A statement of purpose and patient's guide were in place and Mrs Quinn confirmed that these documents will be kept under review when and updated as necessary.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place.

Notifiable Events/Incidents

An incident management policy and procedure was in place which included the reporting arrangements to RQIA. However, it was identified that the procedural guidance did not clearly state the nature of incident that should be reported to RQIA and the timeframe in which the notification should be submitted. Advice and guidance was provided and following the inspection Mrs Quinn informed RQIA that the incident management policy had been further developed to clearly outline show what needs to be reported to the RQIA and how and when this is to be completed. RQIA were assured that all relevant incidents will be reported to RQIA and other relevant organisations in accordance with legislation and RQIA [Statutory Notification of Incidents and Deaths](#).

During the inspection Mrs Quinn confirmed that any learning from incidents would be discussed with staff. There was a process in place for analysing incidents and events to detect potential or actual trends or weakness in a particular area in order that a prompt and effective response can be considered at the earliest opportunity. An audit would be maintained, reviewed and the findings presented to the directors during their quarterly meetings.

Complaints Management

Review of the complaints policy and procedure confirmed that in the main it was in accordance with the Department of Health (DoH) guidance on complaints handling [Health and Social Care Complaints Procedure \(Revised April 2023\)](#) and [The Independent Health Care Regulations \(Northern Ireland\) 2005](#). However it was identified that the role of RQIA within the complaints management process required clarification. Advice and guidance was provided and following the inspection RQIA received confirmation that the complaints policy had been amended to ensure complainants were aware that the role of RQIA is solely regulatory.

During the inspection it confirmed that a copy of the complaints procedure is made available for patients/and or their representatives on request and staff demonstrated a good awareness of complaints management.

Optimax Clinic Limited has a customer services and complaints handling department who manage all complaints received. Mrs Quinn confirmed that complaints received since the previous inspection had been investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome and any action taken.

Mrs Quinn demonstrated that any learning outcomes identified from the investigation of complaints received across the organisation will be used to improve the quality of services provided.

Overall, the governance structures within the clinic provided the required level of assurance to the senior management team and the MAB.

5.2.10 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with staff.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
Total number of Areas for Improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mrs Quinn, Registered Manager, as part of the inspection process and can be found in the main body of the report.

Appendix 1

27 February 2024

Laser Protection Report

Site Details:

Optimax
7 Derryvolgie Avenue
Belfast
BT9 6FL

Laser Protection Adviser appointed by site:

Julie Robinson, UCLH

Laser/IPL Equipment:

Make	Model	Class	Serial Number	Wavelength(s)
Schwind	Amaris	4	S244	193 nm (ArF)
Intralase	FS	3B	0506-40039	1053 nm (Nd:Glass)

Introduction

A Laser Protection Adviser inspection of Optimax was performed on 15 February 2024. This report summarises the main aspects of the inspection and document review where improvements may be required. The findings are based on the requirements of the Minimum Care Standards for Independent Healthcare Establishments published July 2014 by the Department of Health, Social Services and Public Safety (DHSSPSNI) and other relevant legislation, guidance notes and European Standards.

The LPA inspection included a review of:

- Protective eyewear
- Environment/signage
- Training records and user authorisation
- Laser device markings
- Maintenance Records
- Treatment protocols
- Risk assessments
- Local rules
- Appointment of duty holders (LPS/LPA)

Comments / Recommendations:

1. **Laser Local Rules for Intralase FS laser:** The 'Emergency Procedure' section of the Intralase FS laser local rules refer to reporting incidents to Medicines and Healthcare products Regulatory Agency (MHRA), however adverse incidents in Northern Ireland should be reported to the Northern Ireland Adverse Incident Centre (NIAIC). The local rules should be updated to include the specific requirements within Northern Ireland.
2. **Local Rules Declarations:** It was noted that a visiting member of Optimax staff covering a clinic had not signed to confirm they had read the local rules, however during a discussion with the Laser Protection Supervisor, they indicated that the staff member had read the local rules. The clinic should ensure that that all staff working in the laser controlled area, including visiting staff have signed to confirm they have read the local rules.

The clinic should inform RQIA when the above points have been addressed.



Mrs Jane Brown

Laser Protection Adviser to RQIA



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