



The Regulation and  
Quality Improvement  
Authority

**THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY**  
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## Variation of registration report

<b>Inspection No:</b>	<b>21173</b>
<b>Name of Establishment:</b>	<b>Optimax Laser Eye Clinic</b>
<b>Inspector's Name:</b>	<b>Winnie Maguire</b>
<b>Date of Inspection:</b>	<b>31 March 2015</b>

## 1.0 General Information

<b>Name of establishment:</b>	Optimax Laser Eye Clinic
<b>Address:</b>	7 Derryvolgie Avenue Belfast BT9 6FL
<b>Telephone number:</b>	028 9066 1118
<b>Registered Organisation/Registered Provider:</b>	Optimax Laser Eye Clinic James Rowley (registration pending )
<b>Registered Manager:</b>	Susan Moffatt
<b>Person-in-charge of the establishment at the time of inspection:</b>	Susan Moffatt
<b>Registration Category:</b>	PT(L) - Prescribed techniques or prescribed technology: establishments using Class 3b or Class 4 lasers PD – Private Doctor
<b>Date and time of inspection:</b>	31 March 2015 10:00-13:30
<b>Name of inspector:</b>	Winnie Maguire
<b>Names of Medical Physics Advisors:</b>	Dr Ian Gillan Louise Sarri (Trainee Clinical Scientist)

## **2.0 Introduction**

The Regulation and Quality Improvement Authority (RQIA) is empowered under the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to inspect independent health care establishments. A minimum of one inspection per year is required and this may be announced or unannounced.

## **3.0 Purpose of Variation of Registration Inspection**

The purpose of the variation of registration inspection is to determine compliance with:

- The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005;
- The Independent Health Care Regulations (Northern Ireland) 2005; and
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

The inspection will also determine that persons applying to be registered with RQIA have knowledge of the above legislation and the DHSPPS Minimum Care Standards for Healthcare Establishments, July 2014. The inspection also sought to conclude the process to determine the fitness of the applicant registered person(s) in the form of an interview.

## **4.0 Methods/Processes**

The methods/process used in this inspection included the following:

- review of the submitted application forms and supported documentation;
- discussion with Susan Moffatt, registered manager;
- discussion with staff;
- fit persons interview with James Rowley;
- assessment of the environment;
- review of documentation required by legislation and good practice; and
- evaluation and feedback.

## 5.0 Profile of the Establishment

Optimax Laser Eye Clinic is located in an extensively converted residential building located in south Belfast.

Private car parking is available for patients.

The establishment is accessible for patients with a disability.

A waiting area and toilet facilities are available for patients use.

The establishment's statement of purpose outlines the range of services provided.

### Laser Equipment

Two lasers are in use

**Manufacturer:** Schwind

**Model:** Amaris 750

**Serial Number:** 5244

**Laser Class:** 4

**Manufacturer:** Intralase

**Model:** FS/F530

**Serial Number:** 0506-40039

**Laser Class:** 3B

### Laser Protection Advisor (LPA)

Dr Sandy Mosse

### Laser Protection Supervisor (LPS)

Susan Moffatt

### Medical support services

Clinical Director Optimax Ltd

### Clinical Authorised Users

Dr S Mughal

Dr M Ghassan Ayoubi

### Non-clinical Authorised Users

Susan Moffatt

Fiona Quinn

Valerie Smyth  
Kelly Braniff  
Donna–Marie Kempton (in training)

**Type of Treatments Provided**

Photorefractive keratectomy (PRK)  
Lasik  
Epi-lasek

The clinic moved premises in March 2015.

Susan Moffatt has been the registered manager since 2006.

James Rowley has applied to be the registered person for Optimax Laser Eye Clinic.  
The registration is pending.

## 6.0 Summary

An application was submitted to RQIA by Optimax Laser Eye Clinic for a variation of registration as the establishment was moving premises. An application was also submitted for the registration of James Rowley as registered provider.

The application forms and supporting documentation was reviewed as part of the inspection process.

The inspection was carried out by Winnie Maguire accompanied by Dr Ian Gillan LPA for RQIA and Louise Sarri Trainee Clinical Scientist on 31 March 2015 between the hours of 10:00 and 13:30.

Susan Moffatt was available during the inspection and for verbal feedback at the conclusion of the inspection.

During the course of the inspection the inspector discussed operational issues, examined a selection of records and carried out a general inspection of the establishment.

A Statement of Purpose and Patient Guide were in place which reflected legislative and best practice guidance.

Systems were in place to obtain the views of patients as before.

The establishment had a complaints policy and procedure in place which was found to be in line with the DHSSPS guidance on the management of complaints within regulated establishments and agencies. Systems were in place to effectively document and manage complaints.

A review of training records confirmed that authorised users had completed the required mandatory training. Staff not involved in the use of the laser had received laser safety awareness training.

Staff had undertaken an induction and orientation programme to the new premises. A record of induction was established on inspection.

There was a policy and procedure in place for infection prevention and control (IPC). A comprehensive IPC audit had been carried out. The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor. Staff had received training in infection prevention and control. Cleaning schedules were in place.

The patient journey was discussed and found to be in line with patients' needs. The patient documentation will remain the same including care records.

The establishment has medical treatment protocols in place written by Clinical Director for Optimax Ltd on March 2015. A requirement was made to include permitted variations on laser settings for particular surgeons.

The establishment has local rules developed by their LPA and written on 30 March 2015.

A risk assessment of the premises was undertaken by the LPA on March 2015 and all issues identified have addressed by the LPS.

There was list of authorised users in place.

Whilst the environment in which the lasers are to be used was found to be safe and controlled, the demarcation of the controlled area should be clear and outlined in the local rules. A recommendation was made on this matter. Protective eyewear was available for the operator as outlined in the local rules. There was a variance in practice on the use of protective eyewear and the information outlined in the local rules. A recommendation was made to clarify this matter with the LPA. Laser safety warning signs are displayed when the lasers is in use as described within the local rules.

Arrangements are in place to ensure that the laser keys are stored safely and securely when the equipment is not in use.

The inspector discussed the regulatory obligations of a registered provider with James Rowley in respect of the relevant legislation and the draft minimum standards. Mr Rowley evidenced a clear understanding of his role in this regard and registration as registered provider is recommended.

One requirement and two recommendations were made as a result of the variation of registration inspection, details can be found in the main body of the report and the attached Quality Improvement Plan (QIP).

Dr Ian Gillan's report is attached and issues highlighted should be addressed.

Overall the establishment was found to be providing a safe and effective service.

Information has been gathered throughout the registration process. Some of the matters set out above have been found to not yet be in place. These matters have been discussed with Susan Moffatt. The requirement and recommendations relating to these matters have been made in the inspection report. A timescale that has been agreed with Susan Moffatt is specified for submission to RQIA of a Quality Improvement Plan (QIP) addressing these matters. Scrutiny of this information means that the variation of registration of this independent hospital is recommended, subject to submission to RQIA of a QIP agreeing that these matters will be addressed within the specified timescales.

The inspector wishes to thank Susan Moffatt and staff for their helpful discussions, assistance and hospitality throughout the inspection process.

## **7.0 Inspection Findings**

### **7.1 Statement of purpose**

A statement of purpose was prepared in a recognised format which covered the key areas and themes outlined in regulation 7, schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005.

### **7.2 Patient Guide**

A Patient Guide was prepared in a recognised format which covered the key areas and themes specified in regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005.

### **7.3 Patient Partnerships**

The establishment will continue to obtain the views of service users on the quality of treatment, information and care received using patient satisfaction survey following consultation, treatment and review.

The information obtained from patients is collated into an anonymised format, summarised and used by the establishment to make improvements to the services.

A copy of the summary report will be made available to patients and other interested parties.

### **7.4 Complaints**

The establishment operates a complaints policy and procedure in accordance with the Department of Health, Social Services and Public Safety (DHSSPS) guidance on complaints handling in regulated establishments and agencies (April 2009) and the Independent Health Care Regulations (Northern Ireland) 2005.

Systems are in place to effectively document and manage complaints.

### **7.5 Staff Training and Development and Training for Staff using Lasers**

A record of training was available for all authorised users which confirmed Core of Knowledge and application training had been undertaken.

A review of the training records confirmed that all mandatory training outlined in the RQIA guidance had been completed.

Laser safety awareness training has been provided for staff not directly involved in the use the laser.

Staff had undertaken an induction and orientation programme to the new premises. A record of induction was established on inspection.



## **7.7 Infection Prevention and Control**

The establishment has policies and procedures in place for infection prevention and control (IPC).

A comprehensive IPC audit had been carried out.

The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor.

Staff had received training in infection prevention and control.

Cleaning schedules were in place.

There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available.

## **7.8 Patient Information and Laser Procedures**

The patient journey was discussed and found to be in line with patients' needs. The patient documentation will remain the same including care records.

## **7.9 Procedures for the User of Lasers and Intense Light Sources**

The establishment has medical treatment protocols in place written by Clinical Director for Optimax Ltd on March 2015. A requirement was made to include permitted variations on laser settings for particular surgeons.

The medical treatment protocol sets out:

- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- Recognition of treatment-related problems
- Procedure if anything goes wrong with treatment
- Procedure in the event of equipment failure.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis.

The establishment has local rules in place which have been developed by their LPA on March 2015.

Systems are in place to review the local rules every three years.

The local rules cover:

- The potential hazards associated with lasers and intense light sources
- 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

The name of the person who has overall on-site responsibility for safety during laser treatments is recorded within the local rules.

A list of clinical and non- clinical authorised users is maintained and authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

A register is maintained for every time the lasers are operated and includes:

- The name of the person treated
- The date
- The operator
- The treatment given
- The precise exposure
- Any accident or adverse incidents

The laser register was reviewed and found to contain all of the information required by legislation.

The format of patient care records is unchanged and was therefore not reviewed on this occasion.

## **7.10 Safe Operation of Lasers and Intense Light Sources**

Whilst the environment in which the lasers are to be used was found to be safe and controlled. The demarcation of the controlled area should be clear and outlined in the local rules. A recommendation was made on this matter.

When the equipment is in use, the safety of all persons in the controlled area is the responsibility of Susan Moffatt, the LPS.

Laser safety warning signs are displayed when the lasers are in use and removed when not in use as described within the local rules.

Protective eyewear was available for the operator as outlined in the local rules. There was a variance in practice on the use of protective eyewear and the information outlined in the local rules. A recommendation was made to clarify this matter with the LPA.

Entrance doors are locked to enable access to the locked room in the event of an emergency.

There are formal written arrangements in place for the safe custody of the laser key. The laser key was observed to be stored safely and securely during the inspection.

There is a laser safety file in place.

Equipment is serviced and maintained in line with the manufacturers' guidance. The most recent service reports were reviewed as part of the inspection process.

The inspector reviewed the incident policy and discussed the reporting of adverse incidents in line with the RQIA reporting procedure.

## **8.0 Fit Person Interview**

Providers of regulated establishments require to be registered with RQIA in accordance with Article 12 of The Health and Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, as it is an offence to carry on an establishment of any description without being registered in respect of it.

James Rowley submitted an application to RQIA to become the registered provider of Optimax Laser Eye Clinic. The relevant information, supporting documentation and appropriate fees accompanied the application.

Discussion with James Rowley evidenced that he had a clear understanding of his role and responsibilities as a registered provider under the relevant legislation and minimum standards. The following issues were discussed:

- the Statement of Purpose and Patient Guide;
- the management of complaints;
- notification of untoward incidents to RQIA and other relevant bodies;
- quality assurance measures to monitor and improve practice as appropriate;
- protection of vulnerable adults
- responsibilities under the Independent Health Care Regulations (Northern Ireland) 2005
- responsibilities under The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- responsibilities under the draft DHSSPS Independent Health Care Minimum Standards for Hospitals and Clinics
- responsibilities under health and safety legislation.
- responsibilities for the safe use and operation of the laser

- Adherence to professional codes of conduct (if applicable)
- Any court cases pending/disciplinary cases with employers/professional regulatory bodies.

Registration of James Rowley with RQIA as registered provider is recommended.

## **9.0 Laser Protection Report**

A laser protection report prepared by Dr Ian Gillan, RQIA's medical physics expert has been appended to this report and outlines any deficits in laser safety arrangements within the establishment.

## 10.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Susan Moffatt as part of the inspection process.

The timescales commence from the date of inspection.

Requirements are based on The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011

Recommendations are based on the Department of Health, Social Services and Public Safety's draft Independent Health Care Minimum Standards for Hospitals and Clinics, promote good practice and should be considered by the management of the establishment to improve the quality of service experienced by clients.

The registered provider/manager is required to record comments on the Quality Improvement Plan.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the Authority would apply standards current at the time of that application.

Enquiries relating to this report should be addressed to:

**Regulation and Quality Improvement Authority**  
**9th Floor**  
**Riverside Tower**  
**5 Lanyon Place**  
**Belfast**  
**BT1 3BT**



## Quality Improvement Plan

### Variation of Registration Inspection

Optimax Laser Eye Clinic

31 March 2015

The areas where the service needs to improve, as identified during this inspection visit, are detailed in the inspection report and Quality Improvement Plan.

The specific actions set out in the Quality Improvement Plan were discussed with Susan Moffatt during the inspection visit.

Any matters that require completion within 28 days of the inspection visit have also been set out in separate correspondence to the registered persons.

**Registered providers / managers should note that failure to comply with regulations may lead to further enforcement and/ or prosecution action as set out in The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.**

It is the responsibility of the registered provider / manager to ensure that all requirements and recommendations contained within the Quality Improvement Plan are addressed within the specified timescales.


Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

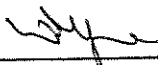
**RECOMMENDATIONS**

These recommendations are based on the DHSPPS Minimum Care Standards for Healthcare Establishments, July 2014, research or recognised sources. They promote current good practice and if adopted by the registered person/manager may enhance service, quality and delivery.

NO.	MINIMUM STANDARD REFERENCE	RECOMMENDATIONS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	48	The registered person should ensure clarification is sought on the demarcation of the controlled area and outlined in the local rules.  <b>Ref 7.10</b>	One	ACTIONED	Immediate
2	48	The registered person should clarify the use of protective eyewear with the LPA and ensure it is clearly outlined in the local rules.  <b>Ref 7.10</b>	One	ACTIONED	Immediate

Please complete the following table to demonstrate that this Quality Improvement Plan has been completed by the registered manager and approved by the responsible person / identified responsible person and return to [independent.healthcare@rqia.org.uk](mailto:independent.healthcare@rqia.org.uk)

Name of Registered Manager Completing QIP	Muhammad
Name of Responsible Person / Identified Responsible Person Approving QIP	 JAMES ROWLEY

QIP Position Based on Comments from Registered Persons	Yes	Inspector	Date
Response assessed by inspector as acceptable	✓		11/4/15
Further information requested from provider			