

The Regulation and

Announced Inspection

Name of Establishment:	Optimax Laser Eye Clinic
Establishment ID No:	10628
Date of Inspection:	18 November 2014
Inspector's Name:	Winnie Maguire
Inspection No:	17385

The Regulation and Quality Improvement Authority 9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT Tel: 028 9051 7500 Fax: 028 9051 7501

1.0 General Information

Name of establishment:	Optimax Laser Eye Clinic
Address:	438 Lisburn Road Belfast BT9 6GR
Telephone number:	028 9066 1118
Registered organisation/ registered provider:	Optimax Laser Eye Clinic Mr R K Ambrose
Registered manager:	Mrs Susan Moffatt
Person in charge of the establishment at the time of inspection:	Mrs Susan Moffatt
Registration category:	PT(L) Prescribed techniques or prescribed technology: establishments using Class 3b or Class 4 lasers PD – Private Doctor
Date and time of inspection:	18 November 2014 10.00 - 13.45
Date and type of previous inspection:	Announced Inspection 24 September 2013
Name of inspector:	Winnie Maguire
Name of Medical Physics Advisor:	Dr Ian Gillan

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.

This is a report of the announced inspection to assess the quality of services being provided. The report details the extent to which the regulations and DHSPPS Minimum Care Standards for Healthcare Establishments, July 2014, measured during the inspection were met.

2.1 Purpose of the Inspection

The purpose of this inspection was to ensure that the service is compliant with relevant regulations, the minimum standards and to consider whether the service provided to patients was in accordance with their assessed needs and preferences. This was achieved through a process of analysis and evaluation of available evidence.

RQIA not only seeks to ensure that compliance with regulations and standards is met but also aims to use inspection to support providers in improving the quality of services. For this reason, inspection involves in-depth examination of an identified number of aspects of service provision.

The aims of the inspection were to examine the policies, procedures, practices and monitoring arrangements for the provision of refractive and laser eye surgery, and to determine the provider's compliance with the following:

- The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments

Other published standards which guide best practice may also be referenced during the inspection process.

2.2 Method/Process

Committed to a culture of learning, RQIA has developed an approach which uses self-assessment, a critical tool for learning. The self-assessment was forwarded to the provider prior to the inspection and was reviewed by the inspector prior to the inspection. The inspection process has three key parts; self-assessment, pre-inspection analysis and the visit undertaken by the inspector.

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Specific methods/processes used in this inspection include the following:

- Analysis of pre-inspection information and self-assessment
- Discussion with the registered manager, Susan Moffatt
- Examination of records
- Tour of the premises
- Evaluation and feedback

Any other information received by RQIA about this registered provider and its service delivery has also been considered by the inspector in preparing for this inspection.

The completed self- assessment is appended to this report.

2.3 Consultation Process

During the course of the inspection, the inspector:

Spoke with staff	1

2.4 Inspection Focus

The inspection sought to establish the level of compliance being achieved with respect to the following DHSPPS Minimum Care Standards for Healthcare Establishments and to assess progress with the issues raised during and since the previous inspection.

- Standard 5 Patient and Client Partnerships
- Standard 7 Complaints
- Standard 9 Clinical Governance
- Standard 11 Practising Privileges
- Standard 16 Management and Control of Operations
- Standard 48 Laser and Intense Light Sources

3.0 Profile of Service

Optimax Laser Eye Clinic is in a converted residential building located in south Belfast. The establishment offers a range of services including laser refractive eye surgery.

Laser Equipment

Manufacturer: Laser Class: Model: Serial Number:	Nidex EC-5000 4 Argonfluride Excimer Laser 51088	
Manufacturer: Laser Class:	Intralase 3B	
Model:	Nd YLF 1053	
Serial Number:	050649939	
Laser Protection A	Advisor (LPA)	Laser Protection Service Department of Medical Physics and Bioengineering University College London Dr Sandy Mosse
Laser Protection S	Supervisor (LPS)	Susan Moffatt
Medical Support S	Services	Clinical Director Optimax Ltd
Clinical Authorise	d Users	Dr S Mughal Dr M Ghassan Ayoubi

Non Clinical Authorised Users

Susan Moffatt	Fiona Quinn
Kelly Braniff	Valerie Smyth

Types of Treatment Provided

Photorefractive keratectomy (PRK) Lasik Epi-Lasek

Private car parking is available for patients and visitors.

The establishment is accessible for patients with a disability.

Susan Moffatt has been the registered manager since 2006.

Optimax Laser Eye Clinic is registered as an independent hospital with the PT(L) and PD categories of registration.

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4.0 Summary of Inspection

An announced inspection was undertaken by Winnie Maguire accompanied by Dr Ian Gillan (LPA for RQIA) and Elisa Tweedie (RQIA) was also in attendance on 18 November 2014 from 10.00 to 13.45. The inspection sought to establish the compliance being achieved with respect to The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011, the DHSSPS Minimum Care Standards for Independent Healthcare Establishments and to assess the progress made to address the issues raised during the previous inspection.

There were three recommendations made as a result of the previous annual announced inspection on 24 September 2013. All of the recommendations have been fully addressed.

The inspection focused on the DHSSPS Minimum Care Standards for Independent Healthcare Establishments outlined in section 2.4 of this report.

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.

The establishment has robust systems in place to obtain the views of patients on a formal and informal basis. The inspector reviewed the patient satisfaction survey and found that patients were highly satisfied with the care and treatment provided.

Optimax Laser Eye Clinic has a complaints policy and procedure in place which was found to be line with the DHSSPS guidance and legislation. The inspector reviewed complaints management within the establishment and found that complaints were well documented, fully investigated and had outcomes recorded. The registered manager displayed a good understanding of complaints management.

There is a defined management structure within the establishment and clear lines of accountability. The registered manager is responsible for the day to day running of the establishment and ensuring compliance with the legislation and standards.

A recommendation was made to devise a policy which outlines the arrangements in place to fulfil regulation 26 visits by registered provider. This policy was forwarded to the inspector following inspection and on review was found to be satisfactory. Therefore this recommendation has been addressed.

The establishment has systems in place to audit the quality of service provided as outlined in the main body of the report.

The inspector also reviewed incident management and found this to be line with legislation and best practice.

The inspector reviewed the Whistle blowing policy and procedure and found it to be in line with legislation and best practice.

A recommendation was made to devise a written policy in relation to the absence of the registered manager in line with legislation and best practice. This policy was forwarded to the inspector following inspection and on review was found to be satisfactory. Therefore this recommendation has been addressed.

The registered manager undertakes ongoing training to ensure that they are up to date in all areas relating to the provision of services.

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

The inspector reviewed the insurance arrangements for the establishment and found that current insurance policies were in place.

The inspector reviewed the personnel files of two medical practitioners and found them to contain all of the information required by legislation. The medical practitioners were appropriately qualified to provide the laser refractive eye surgery services within the establishment.

There are formal systems in place for granting, maintaining, suspending and withdrawing practising privileges. The inspector reviewed completed practising privileges agreements as part of the inspection process.

Patients are provided with detailed written information regarding the establishment and the type of refractive eye surgery available, the risks, complications and expected outcomes. The cost of treatment is agreed with the individual patient and may vary depending on the patient's prescription and treatment options available.

There were clear medical treatment protocols and local rules in place. Systems are in place to review the medical treatment protocols and local rules on an annual basis. A service level agreement was in place between the establishment and the LPA.

The establishment has a laser register which is completed every time the equipment is operated. The inspector reviewed the register and found it to be comprehensively completed.

The inspector reviewed six patient care records and found them to be comprehensively completed with signed consent forms and patient health

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questionnaires completed. The patient pathway was clearly identified from the initial consultation, through pre-operative, intra-operative and postoperative care. Systems are in place for the ongoing review of patients following surgery. Patients are provided with post-operative instructions and emergency contact numbers should they have any concerns.

A risk assessment had been undertaken by the establishment's LPA in August 2014 and no issues were identified.

Review of the training records confirmed that mandatory training was up to date and authorised users had received appropriate training in the safe use and operation of the laser equipment. Other staff working in the establishment, but not directly involved in the use of laser equipment, have received laser safety awareness training.

The environment in which the laser equipment is used was found to be safe and controlled.

Laser safety warning signs are displayed when the laser equipment is in use. The laser equipment is operated using a key. Arrangements are in place for the safe custody of the laser key when not in use.

Systems were in place to service and maintain the laser equipment in line with the manufacturers' guidance. The most recent service report was reviewed by the inspector. A laser safety file was in place.

The certificate of registration was clearly displayed in the reception area of the establishment.

No requirements and or recommendations were made as a result of this inspection.

Dr Ian Gillan's report is appended and any action outlined must be addressed.

Overall, on the day of inspection, the establishment was found to be providing a quality, safe and effective service to patients and displayed a high level of laser protection arrangements.

The inspector would like to extend her gratitude to Susan Moffatt and the staff of Optimax Laser Eye Clinic for their hospitality and contribution to the inspection process.

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5.0 Follow up on Previous Issues

No.	Minimum Standard Ref.	Recommendations	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	C16	The registered manager should amend the policy and procedure on management of records to include the retention of records timescales in line with the legislation.	The management of records policy now includes retention of records timescales in line with the legislation.	One	Compliant
2	C16	The registered manager should enhance document control for all regulatory records.	The inspector noted good document control arrangements in place.	One	Compliant
3	P2	The registered manager should ensure the local rules are revalidated at least annually and written confirmation of same from the LPA is in place.	Local rules had been written in August 2014 and confirmation of the LPA was in place.	One	Compliant

6.0 Inspection Findings

STANDARD 5		
Patient and Client Partnerships:	The views of patients and clients, carers and family members are obtained and acted on in the evaluation of treatment, information and care	
Optimax Laser Eye Clinic obtains the views of patients on a formal and informal basis as an integral part of the service they deliver.		
treatment and review. T patient feedback. High	online patient satisfaction survey following consultation, he inspector reviewed monthly summary reports of collated level of satisfaction with the treatment and overall service no narrative comments from patients.	
The results of the survey are reviewed by the management team within the clinic and an action plan is developed and implemented if any issues are identified. However no issues were identified as requiring to be addressed.		
The information received from the patient survey is collated into an annual summary report which is made available to patients and other interested parties to read in the patient guide.		
Evidenced by:		

Review of patient satisfaction surveys Review of summary report of patient satisfaction surveys Summary report made available to patients and other interested parties Discussion with staff

STANDARD 7		
Complaints:	All complaints are taken seriously and dealt with appropriately and promptly.	
The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies and the legislation. The registered manager demonstrated a good understanding of complaints management.		
All patients are provided with a copy of the complaints procedure, which is contained within the Patient Guide. The registered manager confirmed that the complaints procedure could be made available in alternative formats and languages if required.		
The inspector reviewed the complaints register and complaints records. All complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation.		
The registered manager undertakes an audit of complaints regularly. The audit information is used to identify trends and enhance services provided as part of the establishment's clinical governance arrangements.		
Evidenced by:		

Evidenced by:

Review of complaints procedure Complaint procedure made available to patients and other interested parties Discussion with staff Review of complaints records Review of the audit of complaints

STANDARD 9	
Clinical Governance:	Patients and clients are provided with safe and effective treatment and care based on best practice guidance, demonstrated by procedures for recording and audit.

The registered manager ensures the establishment delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards.

Discussion with the registered manager and review of training records confirmed that systems are in place to ensure that staff receive appropriate training when new procedures are introduced.

The establishment has systems in place to audit the quality of service provided. The inspector reviewed the following audits as part of the inspection process:

- Monthly patient notes audit
- Weekly cleaning audit
- Complaints audit
- Infection prevention and control (IPC) audit
- Unannounced IPC audit
- Quarterly medication audit
- Monthly patient satisfaction audit

Systems are in place to ensure that the registered provider is kept informed regarding the day to day running of the establishment.

A recommendation was made to devise a written policy outlining arrangements that comply with regulation 26 - visits by registered provider. The inspector was informed senior management from Optimax's headquarters visit regularly and provides a written report of their visits to the registered provider. The policy was forwarded to the inspector following inspection and on review was found to be satisfactory. Therefore this recommendation has been addressed.

Systems are in place to ensure that the quality of services provided by the clinic is evaluated on an annual basis and discussed with relevant stakeholders.

There are clear arrangements for monitoring the quality of clinical care that include the following indicators:

- Unplanned returns to theatre
- Unplanned transfers to other hospitals
- Adverse clinical incidents
- Post-operative infection rates for the establishment

The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.

The inspector reviewed incident management and found that incidents were documented, fully investigated and had outcomes recorded.

Audits of incidents are undertaken and learning outcomes are identified and disseminated throughout the organisation.

The registered manager confirmed that no research is currently being undertaken within the establishment.

Evidenced by:

Review of policies and procedures Discussion with registered manager Review of monitoring reports Review of audits Review of incident management Review of research arrangements

STANDARD 11			
Practising Privileges:	Medical practitioners may only use facilities in the establishment for consultation with and treatment of patients if they have been granted practising privileges.		
Opitmax Laser Eye Clinic has a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.			
Medical practitioners meet with Medical Director of Optimax prior to privileges being granted.			
The inspector undertook and confirmed that:	The inspector undertook a review of the personnel files of two medical practitioners and confirmed that:		
 There was eviden (GMC) The medical pract indemnity insuran The medical pract in ophthalmic lase Evidence of enhal There was eviden medical education GMC There was eviden appraiser Written agreement 	titioners have provided evidence of experience in experience er eye surgery procedures (Lasik and Lasek) nced Access NI disclosure check nce of ongoing professional development and continuing in that meet the requirements of the Royal Colleges and nce of ongoing annual appraisal by a trained medical nt between each medical practitioner and the establishment ms and conditions of practising privileges which has been		
The inspector confirmed that each medical practitioner has an appointed responsible officer.			
There are systems in place to review practising privileges agreements every two years.			
Evidenced by: Review of practising privileges policy and procedures Review of practising privileges agreements			

Review of practising privileges agreements Review of medical practitioner's personnel files

Discussion with staff

STANDARD 16	
Management and	Management systems and arrangements are in place
Control of Operations:	that ensure the delivery of quality treatment and care.

There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities for all areas of the service.

A recommendation was made to devise a policy and procedure to ensure that RQIA is notified if the registered manager is absence for more than 28 days. The policy should include the interim management arrangements for the establishment. The policy was forwarded to the inspector following inspection and on review was found to be satisfactory. Therefore this recommendation has been addressed.

Review of the training records and discussion with the registered manager confirmed that they undertake training relevant to their role and responsibilities within the organisation.

The inspector reviewed the establishment's Patient Guide and Statement of Purpose and found them to be in line with the legislation.

There is a written policy on "Whistle Blowing" and written procedures that identify to whom staff report concerns about poor practice and the support mechanisms available to those staff.

The inspector discussed the insurance arrangements within the establishment and confirmed current insurance policies were in place. The certificates of registration and insurance were clearly displayed in the reception area of the premises.

Evidenced by:

Review of policies and procedures Review of training records Review of Patient Guide Review of Statement of Purpose Review of insurance arrangements

STANDARD 48Laser and IntenseLight Sources:Light Sources:

Patients have an initial consultation with a fully qualified optometrist who discusses their treatment options and the cost of the surgery. The establishment has a price list available however this may vary depending on the individual prescription of the patient and the surgery options available to them. All patients consent to the cost of treatment prior to surgery.

Patients also have a pre-operative consultation with their surgeon on the planned day of surgery or beforehand, if requested, to discuss their treatment.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by Dr Amir Hamid in 2013. Systems are in place to review the medical treatment protocols on a two yearly basis.

The medical treatment protocols set out:

- Indications
- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- Recognition of treatment related problems
- Procedure if anything goes wrong with the treatment
- Permitted variation on machine variables
- 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 inspector reviewed the service level agreement between the establishment and the LPA which is dated January 2014.

The establishment has local rules in place which have been developed by their LPA in August 2014.

The local rules cover:

- The potential hazards associated with lasers
- Controlled and safe access
- Authorised operator's responsibilities
- Methods of safe working
- Safety checks

- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incidents procedures

The laser protection supervisor has overall responsibility for safety during laser eye surgery as 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.

The establishment has a laser register which is completed every time the equipment is operated and includes:

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

The inspector reviewed the laser register during the inspection and found it to be comprehensively completed.

The inspector reviewed the care records of six patients and found them to be comprehensively completed. There was a clear patient pathway recorded within the care records from the initial consultation, to pre-operative, intra-operative and postoperative care. Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

There was evidence of signed consent forms within the care records reviewed which clearly outlined the associated risks and complications of surgery. A completed patient health questionnaire was also available.

Patients are provided with clear post-operative instructions along with contact details for a consultant ophthalmologist if they experience any concerns.

The establishment's LPA completed a risk assessment of the premises in August 2014 and no recommendations were made.

The authorised users have completed training in core of knowledge and the safe use and application of the laser equipment.

Review of the training records confirmed that all authorised users had also undertaken the following required mandatory training in line with RQIA guidance:

- Basic life support annually
- Fire safety annually
- Infection prevention and control annually

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

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

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use, as described within the local rules.

The door to the laser treatment room is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using a key. Arrangements are in place for the safe custody of the laser key when not in use.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports dated 12 August 2014 and 23 October 2014 for both lasers were reviewed as part of the inspection process.

There is a laser safety file in place that contains all of the relevant information relating to the laser equipment.

Evidenced by:

Discussion with staff Review of policies and procedures Review of information provided to patients Review of local rules Review of medical treatment protocols Review of laser register Review of patient care records Review of LPA's risk assessment Review of staff personnel files Review of staff personnel files Review of training records Review of premises and controlled area Review of maintenance records Review of laser safety file

7.0 Quality Improvement Plan

The findings of this inspection were discussed with Susan Moffatt as part of the inspection process.

The inspection resulted in no recommendations or requirements being made.

The registered provider/manager is asked to sign the appropriate page.

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.

Enquiries relating to this report should be addressed to:

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



The **Regulation** and **Quality Improvement Authority**

No requirements or recommendations resulted from the announced inspection of Optimax Laser Eye Clinic which was undertaken on 18 November 2014 and I agree with the content of the report. Return this QIP to <u>Independent.Healthcare@rgia.org.uk</u>.

Please provide any additional comments or observations you may wish to make below:

NAME OF REGISTERED MANAGER COMPLETING	morfalt
NAME OF RESPONSIBLE PERSON / IDENTIFIED RESPONSIBLE PERSON APPROVING	UAWoodlags.

Approved by:	Date
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Optimax Laser Eye Clinic – Annual Announced Inspection – 18 November 2014



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The **Regulation** and **Quality Improvement Authority**

REGULATION AND QUALITY I 27 OCT 2014 IMPROVEMENT AUTHORITY

Pre-Inspection Self-Assessment Laser Refractive Eye Surgery

Name of Establishment:	Optimax Laser Eye Clinic
Establishment ID No:	10628 18 NOVENBER
Date of Inspection:	16 September 2014
Inspector's Name:	Winnie Maguire
Inspection No:	17385

THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY 9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT Tel: 028 9051 7500 Fax: 028 9051 7501

1.0 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.

The aim of inspection is to examine the policies, procedures, practices and monitoring arrangements for the provision of a refractive eye laser service, and to determine the provider's compliance with the following:

- The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- The Department of Health, Social Services and Public Safety's (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments July 2014

Other published standards which guide best practice may also be referenced during the inspection process.

2.0 Self-Assessment

Committed to a culture of learning, RQIA has developed an approach which uses selfassessment.

Where asked in the self-assessment you are required to indicate a yes or no response. You are also asked to provide a brief narrative in the "text box" where applicable.

Following completion of the self-assessment, please return to RQIA by the date specified.

The self-assessment will be appended to the report and made available to the public. No amendments will be made by RQIA to your self-assessment response.

3.0 Self-Assessment Tool

Management of Operations

	YES	NO
Has any structural change been made to the premises since the previous inspection?		NO
Have any changes been made to the management structure of the establishment since the previous inspection?		NO
Yes, please comment		

Policies and Procedures

	YES	NO
Does the establishment have a policy and procedure manual in place which is reviewed at least every 3 years or as changes occur?	YES	
Are the policies and procedures for all operational areas in line with legislation and best practice guidelines?	YES	
Do all policies and procedures contain the date of issue, date of review and version control?	YES	
Are all policies and procedures ratified by the registered person?	YES	
No, please comment		

Records Management

	YES	NO
Does the establishment have a policy and procedure in place for the creation, storage, transfer, retention and disposal of and access to records in line with the legislation?	YES	
Are care records maintained for each individual patient?	YES	
Do the care records reflect the patient pathway from referral to discharge?	YES	
Are arrangements in place to securely store patient care records?	- YES.	
No, please comment		

Patient Partnerships

YES	NO
YES	
YES	
	YES

Medical Emergencies

	YES	NO
Are arrangements in place to deal with medical emergencies?	LES.	
No, please comment		

Complaints

	YES	NO
Does the establishment have a complaints policy and procedure in place which is in line with the legislation and the DHSSPS guidance on complaints handling in regulated establishments and agencies April 2009?	YES	
Are all complaints documented, fully investigated and have outcomes recorded in line with the legislation and the establishment's complaints policy and procedure?	YES	
No, please comment		

Incidents

	YES	NO
Does the establishment have an incident policy and procedure in place which complies with the legislation and RQIA guidance?	YES	
Are all incidents reported, documented, fully investigated and have outcomes recorded in line the legislation, RQIA guidance and the establishment's policy and procedure?	YES	
No, please comment		

Infection Prevention and Control

	YES	NO
Does the establishment have an infection prevention and control policy and procedure in place?	YES	
Are appropriate arrangements in place to decontaminate equipment between patients?	NA	
Does the establishment use single use surgical instruments?	YES	
No, please comment		

Recruitment of staff

	YES	NO
Does the establishment have a recruitment and selection policy and procedure in place?	YES	
Is all information outlined in Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005 retained and available for inspection?	YES	
Have all authorised users (recruited since registration with RQIA) had an enhanced AccessNI disclosure undertaken, prior to commencing employment?	405	
No, please comment		

Mandatory Training

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	YES	NO
Are arrangements in place for all new authorised users to participate in an induction programme?	YES	
Are arrangements in place for medical practitioners and nurses to access continuing professional development opportunities in line with the requirements of their professional bodies?	YES	
Are training records available which confirm that the following mandatory undertaken:	training h	as been
AUTHORISED USERS	YES	NO
Core of knowledge training – within the past 5 year years	YES	
Application training for all equipment and all laser/IPL treatments provided - within the past 5 years	HES	
Infection prevention and control training – annually	YES	
Fire safety – annually	YES	
Basic life support – annually or valid certificate e.g. First Aid at Work which is valid for 3 years	YES	
OTHER STAFF – NOT INVOLVED IN LASER/IPL SERVICES (If applicable)	YES	NO
Laser safety awareness training – annually		No
If No, please comment		
IN LINE WITH LASER LOCAL RULES, ALL PERSON		
WORKING IN THE TREATMENT AREA RECE		0
"CORE OF KNOWLEDGE" TRAINING, EVERY	ZHEN	<8.

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<u>Appraisal</u>

	YES	NO
Does the establishment have an appraisal policy and procedure in		
place?	YES	
Are systems in place to provide recorded annual appraisals for authorised users? (if applicable)	YES.	
No, please comment		

Medical Practitioners and Nurses

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	YES	NO
Are systems in place to ensure medical and nursing staff, who are authorised users, have a current registration with their relevant professional bodies?	YES	
Are policies and procedures in place to grant, review and withdraw practising privilege agreements for medical practitioners?	YES	
Are practising privileges agreements in place for all medical practitioners? (where applicable)	YES	
Are systems in place to ensure that medical practitioners have up to date professional indemnity insurance?	YES	
Are systems in place to ensure that medical practitioners have an annual appraisal undertaken with a trained medical appraiser?	YES	
Are arrangements in place to ensure medical practitioners have a responsible officer?	YES	
No, please comment	- A	

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Lasers/IPL Service

	YES	NO
Does the establishment have a certified Laser Protection Advisor (LPA)?	VES	
Has the establishment an up to date LPA report?	YES	
Has the establishment an up to date risk assessment undertaken by their LPA?	YES	
Does the establishment have up to date local rules in place?	YES	
Does the establishment have up to date medical treatment protocols in place?	YES	
Are systems in place to review local rules and medical treatment protocols on an annual basis?		No
Does the establishment have arrangements in place for a medical support service?	NES	
Does the establishment have a list of authorised users?	YES	
Does the establishment have arrangements in place for maintenance and servicing of equipment in line with manufacturer's guidance?	YES	
Does the establishment have protective eyewear in place, as outlined in the local rules?	YES	
Is the controlled area clearly defined?	YES	
Is the door to the treatment room where the laser/IPL used locked during treatment and can be opened from the outside in the event of an emergency?	YES	
Does the establishment display laser/IPL warning signs as outlined in the local rules?	YES	
Are arrangements in place for the safe custody of laser/IPL keys and/or voad codes?	YES	
es the establishment have a laser/IPL safety file in place?	YES	

Does the establishment have a laser/IPL register(s) in place? NES. No, please comment THE LPA DICTATES THE FREQUENCY OF REVIEWING, THE LASER LOCAL RULES. ALL COLPORATE POLICIES, PROCEDURES AND PROTOCOLS ARE REVIEWED EVERY ZMEARS UNLESS THERE IS A CHANGE IN PRACTICE OR GUIDANCE 12.

4.0 Declaration

To be signed by the registered provider or registered manager for the establishment.

I hereby confirm that the information provided above is, to the best of my knowledge, accurately completed.

Name	Signature	Designation	Date	
SUSANMOHAII	modalt	CLINIC MANAGER.	23.	1



23 October 2014

Tel: 08705 14 33 14 27 OCT 2014 IMPROVEMENT AUTHORITY

Mrs W Maguire Inspector Regulation and Quality Improvement Authority 9th Floor Riverside Tower 5 Lanyon Place Belfast BT1 3BT

Dear Mrs Maguire

Re: Optimax Laser Eye Clinic Announced Inspection 18 November 2014

Further to your recent correspondence, please find enclosed completed Self Assessment document for your attention.

1 look forward to seeing you on 18 November 2014.

Kind regards

Yours sincerely

motal

SUSAN MOFFATT Clinic Manager Encs.