

The Regulation and

Announced Inspection

Name of Establishment:	Optical Express
Establishment ID No:	10634
Date of Inspection:	21 May 2014
Inspector's Name:	Jo Browne
Inspection No:	17473

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:	Optical Express
Address:	32 Donegall Place Belfast
	BT1 5BB
Telephone number:	02890437768
Registered organisation/ registered provider:	Ms Mary Spellman
Registered manager:	Ms Sarah Godfrey (Acting)
Person in charge of the establishment at the time of inspection:	Ms Sarah Godfrey (Acting)
Registration categories:	AH (DS) – Acute hospital day surgery PT (L) – Prescribed techniques or prescribed technology: establishments using Class 3b or Class 4 lasers PD – Private doctor (other)
Date and time of inspection:	21 May 2014 10.00 – 13.15
Date and type of previous inspection:	Announced 4 June 2013
Name of inspector:	Jo Browne
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 draft Independent Health Care Minimum Standards for Hospitals and Clinics 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 draft 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 laser refractive eye services, 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) draft Independent Health Care Minimum Standards for Independent hospitals and clinics.

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

2.2 Methods/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.

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

- Analysis of pre-inspection information and self-assessment
- Discussion with the responsible person, Ms Mary Spellman
- Discussion with the acting manager, Ms Sarah Godfrey
- 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:

Reviewed patient feedback questionnaires,	Reviewed	
issued by the establishment	summary report	
Spoke with staff	2	

2.4 Inspection Focus

The inspection sought to establish the level of compliance being achieved with respect to the following DHSSPS draft Independent Health Care Minimum Standards for Independent Hospitals and Clinics and to assess progress with the issues raised during and since the previous inspection.

- C4 Patient Partnerships
- C5 Complaints
- C10 Management and Control of Operations
- P1 Patient information and Laser Procedures
- P2 Procedures for Use of Lasers and Intense Light Sources
- P3 Training for Staff Using Lasers and Intense Light Sources
- P4 Safe Operation of Lasers and Intense Light Sources
- A5 Practising Privileges

3.0 Profile of Service

The registered provider is DCM Holdings Limited, trading as Optical Express (Laser Eye Clinic).

The central office provides support to multiple clinics throughout England, Scotland, Wales, Northern Ireland, Germany and Holland. There are 26 clinics which can facilitate laser eye surgery.

This report focuses on the laser eye clinic in Belfast, Northern Ireland.

The Clinic

Optical Express is located in a commercial building in Donegall Place in the centre of Belfast. The clinic is close to local amenities and public transport routes. Public car parks are available close by for patients to use.

The premises extend over three floors and patient areas can be reached by means of a passenger platform lift and/or stairs.

The ground floor is where spectacles, contact lenses and miscellaneous visual aids can be purchased and general eye test appointments are carried out.

All areas of the building have been designed to accommodate patients who may have difficulty with mobility. There are disabled toilet facilities and wide access doors and corridors.

The Laser Suite

The laser suite is situated on the first floor and incorporates a patient waiting room, where tea and coffee facilities are available. The consulting rooms are sited to ensure patient privacy. The laser room houses the VisX Star 4 laser which offers Wavefront technology. A Class 3B Femtosecond (Intralase) laser is also available, which allows the clinic to offer a blade free method of eye surgery. The clinic only uses single use instruments which reduces the risk of infection.

The Treatments

Laser eye surgery is designed to meet the optical needs of approximately 70% of spectacle and contact lens wearers who are short sighted, long sighted, with or without astigmatism and who are over 18 years of age. The clinic provides a range of laser eye surgery, offering both LASIK and LASEK treatments.

Laser Equipment

Excimer Laser

VisX
Star 4
0030-4638
5629
ArF (193nm)
Class 4

Intralase Laser

Manufacturer:	Intralase
Model:	IFS
Serial Number:	0107-40185
Output Wavelength:	Nd:Glass (1053nm)
Laser Class:	Class 3B

Laser Protection Advisor (LPA)

Dr Roy Henderson (Bioptica)

Laser Protection Supervisor (LPS)

Ms Gail Caldwell

Medical Support Services

Professor Jan Venter - Clinical Director

Clinical Authorised Users

Mr Evangelos Minos

Non Clinical Authorised Users

Ms Gail Caldwell Ms Wendy Coffey Ms Helga Walsh

Optical Express is registered as an independent hospital with the AH (DS), PT (L) and PD categories of registration.

4.0 Summary of Inspection

An announced inspection was undertaken by Jo Browne on 21 May 2014 from 10.00 to 13.15, accompanied by Dr Ian Gillan, Medical Physics Advisor for RQIA. 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 draft Independent Health Care Minimum Standards for Independent hospital and clinics and to assess the progress made to address the issues raised during the previous inspection.

There was one requirement made as a result of the previous annual announced inspection on 4 June 2013 and observations made during the inspection confirmed this had been fully addressed.

The inspection focused on the DHSSPS draft Independent Health Care Minimum standards outlined in section 2.4 of this report.

Ms Mary Spellman and Ms Sarah Godfrey were 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 was in place which reflected legislative and best practice guidance. A requirement was made to ensure that the Patient Guide contained all of the information required by Regulation 8 of The Independent Healthcare Regulations (Northern Ireland) 2005.

The establishment has systems in place to ensure that patients are provided with an opportunity to comment on the quality of care and service provided. The inspector reviewed the patient satisfaction survey and found that patients were highly satisfied.

The establishment's complaints policy and procedure is in 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 responsible individual and acting manager displayed a good understanding of complaints management.

There is a defined management structure within the establishment and clear lines of accountability. The acting manager is responsible for the day to day running of the establishment and ensuring compliance with the legislation and standards. The inspector reviewed the policy and procedures in relation to the absence of the registered manager and whistleblowing. They were found to be in line with legislation and best practice.

The responsible individual and acting manager undertake ongoing training to ensure that they are up to date in all areas relating to the provision of services.

The inspector also reviewed incident management and found this to be line with legislation and best practice. No incidents have been recorded by the establishment since the last inspection; however systems are in place to document and manage and report incidents in line with the legislation.

An audit of all incidents within the organisation is undertaken as part of their clinical governance systems. Arrangements are in place to disseminate learning outcomes throughout the organisation.

Systems are in place for dealing with alert letters and managing lack of competency or poor staff performance. This includes the responsible person and acting manager ensuring that all staff abide by their professional codes of conduct and reporting arrangements to professional bodies if necessary.

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

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.

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

The establishment has medical treatment protocols and local rules in place, a risk assessment had been undertaken by the establishment's LPA. A list of clinical and non-clinical authorised users of the lasers is maintained. The LPS has overall on-site responsibility for safety during laser treatments.

The environment in which the lasers are used was found to be safe and controlled. Laser warning signs are clearly displayed in line with the current legislation. The operation of the lasers is controlled by a key, key card and password access system. Systems are in place to ensure that the laser key and key card are stored securely when the lasers are not in use. The lasers are maintained and serviced in accordance with manufacturers' instructions. The inspector reviewed the most recent service history as part of the inspection process. A laser safety file is retained by the establishment and was found to contain all information in line with the legislation and standards.

There are formal systems in place for applying, granting, maintaining, suspending and withdrawing practising privileges. The inspector reviewed the personnel files of one medical practitioner and found that it contained all of the information required by legislation.

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 certificate of registration was clearly displayed reception area of the laser suite.

There was one requirement made as result of this inspection. This is discussed fully in the main body of the report and in the appended Quality Improvement Plan.

The inspector would like to thank Ms Mary Spellman, Ms Sarah Godfrey and staff of Optical Express for their hospitality and contribution to the inspection process.

5.0 Follow Up on Previous Issues

No.	Regulation Ref.	Requirements	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	18 (2) (a)	The registered manager must ensure medical practitioners who are clinical authorised users undertake the required mandatory training in Basic Life Support, Fire Safety and Infection prevention and control on an annual basis.	Review of training records confirmed that all mandatory training had been completed by the medical practitioner.	One	Compliant

6.0 Inspection Findings

STANDARD C4				
Patient Partnerships:	The views of patients, carers and family members are obtained and acted on in the evaluation of treatment, information and care.			
Optical Express obtains integral part of the service	the views of patients on a formal and informal basis as an ce they deliver.			
establishment. The que and review. The results monthly basis and review areas for improvement a	online patient satisfaction questionnaire while in the estionnaire is completed following consultation, treatment of the patient satisfaction questionnaires are collated on a wed by senior management within the organisation. Any are noted and an action plan developed to address them. mprovement were noted within the recent surveys.			
questionnaires and foun service, care and treatm	the summary report of 351 completed patient satisfaction d that patients were highly satisfied with the quality of ent. A copy of the summary report is made available for ested parties to read in the waiting area of the laser suite.			
•	ly published a new magazine for patients which includes ant journey; copies are available in the waiting area.			
Evidenced by:				
Review of patient satis	faction surveys			

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

STANDARD C5	STANDARD C5				
Complaints: All complaints are taken seriously and dealt with.					
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 responsible individual and acting 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 inspectors 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 establishment undertakes an audit of complaints on a monthly basis as part of the establishment's quality assurance mechanisms. The audit information is used to identify trends and enhance services provided, throughout the whole organisation, as part of the company's clinical governance arrangements.					
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 C10						
Management of Operations:	Management systems and arrangements are in place that support and promote 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.					
	al and acting manager ensure the establishment delivers a e in line with the legislation, other professional guidance and s.					
regarding the day to day	ensure that the registered provider is kept informed running of the establishment. A monthly report is ng manager to the responsible individual.					
notified if the registered	a policy and procedure in place to ensure that RQIA is manager is absence for more than 28 days. The policy nagement arrangements for the establishment.					
	ecords and discussion with the responsible individual and ed that they undertake training relevant to their role and e organisation.					
The inspector reviewed the establishment's Statement of Purpose and found this to be in line with the legislation. The Patient Guide had recently been amended by head office in March 2014 and on review by the inspector some information required by legislation was no longer included. A requirement was made to ensure that the Patient Guide is updated as outlined in Regulation 8 of The Independent Healthcare Regulations (Northern Ireland) 2005.						
	systems in place to audit the quality of service provided. The ollowing audits as part of the inspection process:					
 Audit of patient ca Infection preventi Audit of patient si Complaints audit 	on and control audit mulated collapse					
•	al monitors the quality of services, undertakes a visit to the a report of their findings.					
The establishment has a reporting arrangements	an incident policy and procedure in place which includes to RQIA.					
reporting arrangements establishment since the and manage incidents a	an incident policy and procedure in place which includes to RQIA. No incidents have occurred within the last inspection; however systems are in place to document ppropriately. Audits of incidents are undertaken throughout ed to enhance the quality of care.					

The responsible individual has systems in place to deal with all alert letters issued by the DHSSPS. A file is retained which contains any alerts relevant to Optical Express.

The establishment has arrangements in place to monitor the competency and performance of all staff and report to the relevant professional regulatory bodies in accordance with guidance. The responsible individual and acting manager ensures that all health care professionals adhere to their published codes of professional conduct and professional guidelines.

There are systems in place to check the registration status of health care professionals with their appropriate professional bodies on an annual basis.

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 waiting area of the laser suite.

Evidenced by:

Review of policies and procedures Review of training records Review of Patient Guide Review of Statement of Purpose Discussion with responsible individual/acting manager Review of audits Review of alert letters Review of alert letters Review of competency and professional qualifications Review of incident management Review of insurance arrangements

STANDARD P1	
Patient Information	Patients are clear about what procedures involve, the
and Laser	costs and the skills and experience of those carrying
procedures:	out the procedures.

Optical Express has a dedicated marketing team which ensures that advertising and marketing is factual and not misleading.

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

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.

A copy of the surgeon's profile who will be undertaking the treatment is available on the company's website or at the request of the patient. The profile shows the experience and qualifications of the surgeon.

Patients have a pre-operative consultation with their surgeon on the planned day of surgery or beforehand, if requested, to discuss their treatment. Surgery is normally scheduled to take place approximately two weeks after the initial consultation. If surgery is not undertaken within three months of the initial consultation the patient must have a review before proceeding with surgery. If surgery is not undertaken within six months the patient will have to commence the process again.

The inspector reviewed the care records of five 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 senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

Evidenced by:

Discussion regarding policy on advertising and marketing Review of patient information leaflets Review of surgeon profiles Review of consent forms Review of consultation procedure Review of post-operative arrangements Review of patient records

STANDARD P2Procedures for Use
of Lasers and
Intense LightPatients have laser and intense light source
procedures carried out by, experienced operators, and
in accordance with procedures.Sources:Sources:

Refractive eye surgical procedures are carried out by a consultant ophthalmologist in accordance with medical treatment protocols produced by Jan Venter in December 2013. Systems are in place to review the medical treatment protocols on an annual 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.

The establishment has local rules in place which have been developed by their LPA on 16 April 2014. Systems are in place to review the local rules every three years unless changes occur.

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 refractive 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 an laser register which is completed every time the laser 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.

Evidenced by:

Review of local rules Review of medical treatment protocols Review of laser register

STANDARD P3	
Training for Staff	Patients have laser and intense light source
using Lasers and	procedures carried out by staff that are trained and
Intense Light	experienced in operating Class 3b and 4 lasers and
Sources	intense light sources.

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
- Vulnerable adults every three years

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

For the medical practitioner there was evidence of compliance with the continuing professional development requirements of the relevant professional bodies including Royal Colleges and the General Medical Council (GMC).

Evidenced by:

Review of staff personnel files Review of training records Discussion with staff

STANDARD P4 Safe Operation of Lasers and Intense Light Sources:

The environment in which lasers and intense light sources are used is safe.

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 other 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, as described within the local rules.

The door to the laser suite 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, key card and password. Arrangements are in place for the safe custody of the laser keys and key cards when the lasers are not in use.

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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports of 18 & 28 March 2014 were reviewed as part of the inspection process.

The establishment's LPA completed a risk assessment of the premises on 16 April 2014 and no recommendations were made.

Evidenced by:

Review of premises and controlled area Review of laser safety file Review of maintenance records

STANDARD A5 Practising Privileges: Consultants and other practitioners may only use facilities in the establishment if they have been granted practising privileges. Optical Express has a policy and procedure in place which outlines the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges. A review of the medical practitioner's personnel file confirmed that: • A written agreement between the medical practitioner and the establishment setting out the terms and conditions of practising privileges There was evidence of current registration with the General Medical Council • (GMC) The medical practitioner is covered by the appropriate professional indemnity insurance The medical practitioner has provided evidence of experience in ophthalmic • laser eye surgery procedures (Lasik and Lasek) There was evidence of ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and GMC • There was evidence of ongoing annual appraisal by a trained medical appraiser The inspector confirmed that the medical practitioner has an appointed responsible officer. There are systems in place to review practising privilege agreements every two years. Evidenced by:

Review of practising privileges policy and procedures Review of completed practising privileges agreements Review of medical practitioner's personnel file Discussion with staff

7.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Ms Mary Spellman and Ms Sarah Godfrey as part of the inspection process.

The timescales for completion commence from the date of inspection.

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 RQIA would apply standards current at the time of that application.

Enquiries relating to this report should be addressed to:

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

Jo Browne Inspector / Quality Reviewer

Date



Quality Improvement Plan

Announced Inspection

Optical Express

21 May 2014

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 Ms Mary Spellman and Ms Sarah Godfrey 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.

No.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1.	8 (1)	The responsible person must ensure that the patient guide contains all information outlined in Regulation 8 of The Independent Healthcare Regulations (Northern 9reland) 2005. Ref: Standard C10	One	We have reviewed the patient guide in relation to the requirements detailed in Regulation 8 and have amended our patient information pack (or patient guide) to ensure all the necessary information is included.	Within three months

* , = The registered provider/acting manager is required to detail the action taken, or to be taken, in response to the issue raised in the Quality Improvement Plan. The Quality Improvement Plan is then to be signed below by the registered provider and acting manager and returned to:

Jo Browne

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

SIGNED:	nne.	- SIGNED:	Logodfrey.
NAME:	M SPELLMA	- NAME:	S. GODFREY Acting Manager
DATE	31/7/14	DATE	31/7/14

	QIP Position Based on Comments from Registered Persons	Yes	No	Inspector	Date
A	Quality Improvement Plan response assessed by inspector as acceptable			Berna	718114
В	Further information requested from provider		~	Bronne	718114

Optical Express - Announced Inspection 21 May 2014

3



The Regulation and Quality Improvement Authority

Pre-Inspection Self-Assessment Laser Refractive Eye Surgery

Name of Establishment:	Optical Express
Establishment ID No:	10634
Date of Inspection:	21 May 2014
Inspector's Name:	Jo Browne
Inspection No:	17473

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) draft Independent Health Care Minimum Standards for Hospitals and Clinics

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		No
previous inspection?		
Have any changes been made to the management structure of the establishment since the previous inspection?		No
Yes, please comment		
Our RM is on maternity leave but no long term/permanent changes.		

Policies and Procedures

	YES	NO
Does the establishment have a policy and procedure manual in place	Yes	
which is reviewed at least every 3 years or as changes occur?		
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	Yes	
and version control?		
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	Yes	
creation, storage, transfer, retention and disposal of and access to		
records in line with the legislation?		
Are care records maintained for each individual patient?	Yes	
Do the care records reflect the patient pathway from referral to	Yes	
discharge?		
Are arrangements in place to securely store patient care records?	Yes	
No, please comment	•	

Patient Partnerships

	YES	NO
Does the establishment have systems in place to obtain the views of patients regarding the quality of treatment, care and information provided?	Yes	
Does the establishment make available a summary report of client feedback to patients and other interested parties?	Yes	
No, please comment		

Medical Emergencies

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

<u>Complaints</u>

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

Infection Prevention and Control

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

Mandatory Training

	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	nas 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	Yes	
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		
If No, please comment		

<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

	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		

Lasers/IPL Service

	YES	NO
Does the establishment have a certified Laser Protection Advisor (LPA)?	Yes	
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?	?	
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	Yes	

eypad codes?		
Does the establishment have a laser/IPL safety file in place?	Yes	
Does the establishment have a laser/IPL register(s) in place?	Yes	
lo, please comment The local rules are reviewed every 3 years unless there are chan equipment, environment or uses. The protocol is reviewed annua		

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
Mary Spellman	By email	RGN, ENB346 Surgical Services Manager	1 May 14