

The Regulation and
Quality Improvement
Authority

Cathedral Eye Clinic
RQIA ID: 10705
89-91 Academy Street
Belfast
BT1 2LS

Inspector: Winnie Maguire accompanied by
Dr Ian Gillan, RQIA's Medical Physics Advisor
Inspection ID: IN22117

Tel: 02890322020

**Announced Care Inspection
of
Cathedral Eye Clinic**

24 February 2016

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501 Web: www.rqia.org.uk

1. Summary of Inspection

An announced care inspection took place on 24 February 2016 from 10.00 to 15.00. On the day of the inspection the establishment was found to be delivering safe, effective and compassionate care. The outcome of the inspection found no areas for concern.

This inspection was underpinned by 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 and The Department of Health, Social Services and Public Safety's (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments July 2014.

1.1 Actions/Enforcement Taken Following the Last Care Inspection

Other than those actions detailed in the previous QIP there were no further actions required to be taken following the last inspection.

1.2 Actions/Enforcement Resulting from this Inspection

Enforcement action did not result from the findings of this inspection.

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	0	0

This inspection resulted in no requirements or recommendations being made. Findings of the inspection can be found in the main body of the report.

2. Service Details

Registered Organisation/Registered Person: Cathedral Eye Clinic Ltd Dr Jonathan Moore	Registered Manager: Sheena Maxwell
Person in Charge of the Establishment at the Time of Inspection: Sheena Maxwell	Date Manager Registered: 2 October 2015
Categories of Care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PD Private Doctor	

Laser Equipment**Ophthalmic laser**

Manufacturer: Zeiss
 Model: VISUMAX
 Serial Number: 1048412
 Output wavelength: 1043nm
 Laser Class: 3B
 Location: Third Floor Laser Suite Room

Ophthalmic laser

Manufacturer: Schwind -Amaris
 Serial Number: A779
 Output wavelength: ArF (193nm)
 Laser Class: 4
 Location: Third Floor Laser Suite Room

Yag Photo Disrupter

Manufacturer: NIDEK
 Serial Number: 1048412
 Output wavelength: 1043nm
 Laser Class: 3B
 Location: Second Floor Treatment Room

Ophthalmic laser

Manufacturer: LUMENIS
 Model: Selecta II SLT
 Serial Number: S1883
 Output wavelength: 532nm
 Laser Class: 3B
 Location: Second Floor Treatment Room

Laser Protection Advisor (LPA) – Lasernet – Ms Anna Bass

Laser Protection Supervisor (LPS) – Mr Andrew Spence

Medical Support Services – Professor Jonathan Moore

Clinical Authorised Users – Professor Jonathan Moore (all lasers)
 Mr Colin Willoughby (Lumenis Selecta II SLT laser only)

Non-Clinical Authorised Users – Mr Andrew Spence

Types of Treatment Provided – Refractive laser eye and other vision corrective treatments are carried out

Schwind –Amaris laser

Lasek

Lasik

Trans-epi

PTK

Zeiss Visumax laser

SMILE (Small Incision Lenticule Extraction)

NIDEK YAG laser

YAG laser capsulotomy

Lumenis II SLT laser

SLT (Selective Laser Trabeculoplasty)

3. Inspection Focus

The inspection sought to determine if the following standards have been met:

- Standard 4 – Dignity, Respect and Rights
- Standard 5 – Patient and Client Partnerships
- Standard 7 – Complaints
- Standard 10 – Qualified Practitioners ,Staff and Indemnity
- Standard 48 – Laser and Intense Light Sources

Other areas inspected: Incidents, insurance arrangements and RQIA registration.

4. Methods/Process

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

Prior to the inspection the following records were analysed: pre-inspection information and complaints return.

During the inspection the inspector met with Sheena Maxwell registered manager, Gary McArdle Business Development Manager and Bill Thom Financial Director.

The following records were examined during the inspection:

- | | |
|-----------------------------------|--|
| • Ten patient care records | • Incident/accident records |
| • Laser safety file | • Four sets of local rules |
| • Laser risk assessment | • Medical treatment protocols |
| • Policies and procedures | • Equipment service records |
| • Patient feedback questionnaires | • Complaints records |
| • Training records | • Two medical practitioners
personnel files |

5. The Inspection

5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 15 December 2015.

No requirements or recommendations were made during this inspection.

5.2 Review of Requirements and Recommendations from the last care inspection dated 15 December 2015

As above

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and surgery, with the registered manager and staff confirmed that patients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient and the optometrist. The surgery is provided within a designated laser suite.

Observations confirmed that patient care records were stored securely in locked filing cabinets.

Is Care Effective?

It was confirmed through the above discussion and observation that patients are treated in accordance with the DHSSPS standards for Improving the Patient & Client Experience.

Patients meet with the surgeon on the planned day of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Is Care Compassionate?

Discussion with staff and review of ten patient care records confirmed that patients are treated and cared for in accordance with legislative requirements for equality and rights.

Staff were observed treating patients with compassion, dignity and respect and discussion with patients confirmed this.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.4 Standard 5 – Patient and Client Partnership

Is Care Safe?

Patients are asked for their comments in relation to the quality of treatment provided, information and care received.

The information from patients' comments are collected in an anonymised format, summarised and used by the establishment to make improvements to services.

Is Care Effective?

Cathedral Eye Clinic obtains the views of patients on a formal and informal basis as an integral part of the service they deliver.

The establishment issued feedback questionnaires to patients and seven were returned and completed. Review of the completed questionnaires found that patients were highly satisfied with the quality of treatment, information and care received. Some comments from patients included:

- "Communication was excellent"
- "Very efficient"
- "Very professional"

The information received from the patient feedback questionnaires is collated into an annual summary report which is made available following advice on inspection to patients and other interested parties to read in the reception area of the establishment.

It was confirmed through discussion that comments received from patients are reviewed by management and it was suggested an action plan should be developed and implemented to address any issues identified. This was done on inspection.

Is Care Compassionate?

Review of care records and discussion with staff confirmed that treatment and care is planned and developed with meaningful patient involvement; facilitated and provided in a flexible manner to meet the assessed needs of each individual patient.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.5 Standard 7 - Complaints

Is Care Safe?

Review of complaint records found that complaints are investigated and responded to within 28 working days (in line with regulations) or if this is not possible, complainants are kept informed of any delays and the reason for this.

Discussion with Ms Maxwell confirmed that information from complaints is used to improve the quality of services.

Is Care Effective?

It is not in the remit of RQIA to investigate complaints made by or on the behalf of individuals, as this is the responsibility of the providers. However, if there is considered to be a breach of regulation as stated in The Independent Health Care Regulations (Northern Ireland) 2005, RQIA has a responsibility to review the issues through inspection.

A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice.

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.

Ms Maxwell demonstrated a good understanding of complaints management.

Review of the complaints register and complaints records evidenced that all complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation. Complaints records were observed to be stored securely in line with data protection legislation.

It was suggested to undertake a complaint's audit when necessary and ensure the audit information is used to identify trends and enhance services provided as part of the establishment's quality assurance arrangements.

The complaints procedure is contained within the Patient Guide; copies of which are available in the reception area for patients to read.

Is Care Compassionate?

A copy of the complaints procedure is provided to patients and to any person acting on their behalf.

The complainant is notified of the outcome and action taken by the establishment to address any concerns raised.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.6 Standard 10 – Qualified Practitioners, Staff and Indemnity

Is Care Safe?

Review of two medical practitioner's details confirmed:

- evidence of confirmation of identity
- evidence of current registration with the General Medical Council (GMC)
- the medical practitioners are covered by the appropriate professional indemnity insurance
- the medical practitioners have provided evidence of experience relevant to their scope of practice
- evidence of enhanced AccessNI disclosure check
- evidence of ongoing professional development and continuing medical education that meets the requirements of the Royal Colleges and GMC to ensure the medical practitioner can safely and competently undertake the treatments and services they offer
- evidence of ongoing annual appraisal by a trained medical appraiser
- a responsible officer had been appointed

Arrangements are in place to support medical practitioners, with a licence to practice, to fulfil the requirements for revalidation through providing sufficient information to the responsible officer to support their revalidation, for medical practitioners who are not an employee.

Discussion with Ms Maxwell confirmed that arrangements are in place for dealing with professional alert letters and managing identified lack of competence and poor performance for all staff, including those with practising privileges. There are also mechanisms for reporting incompetence in line with guidelines issued by the Department of Health and professional regulatory bodies.

Is Care Effective?

Discussion with Ms Maxwell confirmed that the medical practitioners are aware of their responsibilities under GMC Good Medical Practice.

The medical practitioners abide by published codes of professional practice relevant to their scope of practice and retain evidence that professional registration and revalidation requirements are met.

Is Care Compassionate?

Discussion with Ms Maxwell demonstrated that the core values of privacy, dignity, respect and patient choice are understood by the medical practitioner providing services within the establishment.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.7 Standard 48 - Laser and Intense Light Sources

Is Care Safe?

Patients have an initial consultation with a fully qualified optometrist who discusses their treatment options and the cost of the surgery.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and was noted to expire on 17 March 2016.

Refractive and other laser eye surgical procedures are carried out by consultant ophthalmologists in accordance with medical treatment protocols produced by Professor Jonathan Moore. 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

The establishment has local rules in place for each laser which have been developed by their LPA on 15 December 2015

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 LPS has overall responsibility for safety during refractive and other 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.

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.

The establishment's LPA completed a risk assessment of the premises in September 2015 and all recommendations made by the LPA have been addressed.

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 areas are clearly defined and not used for other purposes, or as access to areas, when surgery 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.

Protective eyewear is available as outlined in the local rules for laser technicians/surgical assistants.

The doors to the laser suite are 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 lasers' key when not in use.

Is Care Effective?

The establishment has four laser surgical registers which are 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 Lumenis Selecta II SLT laser has not yet been used however there is a laser surgical register available for completion.

Review of the other laser surgical registers during the inspection found them to be comprehensively completed.

The care records of ten patients were reviewed and found 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 post-operative 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 laser eye surgery. A completed patient health questionnaire was also available.

The most recent service reports were reviewed as part of the inspection process. It was noted the Nidek laser was last serviced in April 2014. Ms Maxwell confirmed arrangements were in place to have the laser serviced and maintained in the coming weeks. The other three lasers had been installed or serviced in the last year with appropriate documentation in place. It was suggested the registered manager has an oversight of the servicing arrangements for the lasers to ensure the schedule of maintenance is in line with manufacturer's instructions.

A laser safety file is in place which contains all of the relevant information in relation to the lasers.

Is Care Compassionate?

As previously stated patients meet with their surgeon to discuss their individual surgery and any concerns they may have.

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

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

Areas for Improvement

No areas for improvement were identified during the inspection

Number of Requirements:	0	Number of Recommendations:	0
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5.7 Additional Areas Examined

5.7.1 Management of Incidents

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

No adverse incidents have occurred within the establishment since last inspection. However systems are in place to manage, document, fully investigate incidents and disseminate the outcomes.

5.8.2 RQIA registration and Insurance Arrangements


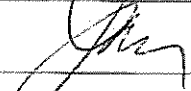

Discussion with Ms Maxwell regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificates of RQIA registration and insurance were clearly displayed in the reception area of the premises.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements	0	Number Recommendations:	0
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No requirements or recommendations resulted from this inspection.

I agree with the content of the report.			
Registered Manager		Date Completed	8/3/16
Registered Person		Date Approved	8/3/16
RQIA Inspector Assessing Response		Date Approved	16/03/16

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

Please ensure this document is completed in full and returned to Independent.healthcare@rqia.org.uk from the authorised email address

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the service. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations.

24th February 2016

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

Dear Mrs Maguire

Laser Protection Report

*The Cathedral Eye Clinic
88 - 91 Academy Street, Belfast BT1 2LS*

Introduction

This report summarises the main deficiencies in the Laser Protection arrangements which were noted during the inspection visit earlier today. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Deficiencies / Comments

Laser Safety File

Although the general laser safety arrangements are of a high standard, the clinic should ensure that the laser safety file contains up to date service records for all four lasers.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Laser Systems

The Cathedral Eye Clinic, Academy Street, Belfast

Ophthalmic Laser

Manufacturer: Zeiss
Model VISUMAX
Serial Number: 1048412
Output wavelength: 1043nm
Laser Class: 3B
Location: Third Floor Treatment Room

YAG Photo disrupter

Manufacturer: NIDEX
Serial Number: 60952
Output wavelength: 1064nm
Laser Class: 3B
Location: Second Floor Treatment Room

Excimer Laser

Manufacturer: Schwind-Amaris
Serial Number: A779
Output wavelength: ArF (193nm)
Laser Class: 4
Location: Third Floor Treatment Room

Ophthalmic Laser

Manufacturer: Lumenis
Model Selecta II SLT
Serial Number: S1883
Output wavelength: 532nm
Laser Class: 3B
Location: Second Floor Treatment Room

Laser Protection Advisor

Anna Bass, Lasermet

Date of last visit 14 July 2015