Announced Inspection

Name of Establishment:	**Cathedral Eye Clinic**
Establishment ID No:	**10705**
Date of Inspection:	**13 February 215**
Inspector's Name:	**Jo Browne**
Inspection No:	**18591**

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:	Cathedral Eye Clinic
Address:	University of Ulster York Street Belfast BT15 1ED
Telephone number:	028 9032 2020
Registered organisation/ registered provider:	Cathedral Eye Clinic Dr Jonathan Moore
Registered manager:	Dr Jonathan Moore
Person in charge of the establishment at the time of inspection:	Mrs Clare McCrory
Registration category:	AH(DS) – Acute Hospital Day Surgery PT(L) – Prescribed Techniques or Prescribed Technology: establishments using Class 3b or Class 4 Lasers
Date and time of inspection:	13 February 2015 14.00 – 17.30
Date and type of previous inspection:	Announced Inspection 14 February 2014
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 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.

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

- Analysis of pre-inspection information and self-assessment
- Discussion with the clinic manager, Mrs Clare McCrory
- Discussion with staff
- 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 the summary report of patient feedback questionnaires, issued by the establishment	55
Spoke with staff	2

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

Cathedral Eye Clinic was initially registered with RQIA on 20 August 2008. The registered person and registered manager is Professor Jonathan Moore. The clinic is located at the University of Ulster, York Street, Belfast and is easily accessible by local transport routes.

The clinic is accessible to patients with a disability.

On street and public car parking is available for patients and visitors.

Laser

Manufacturer : Schwind
System: Excimer
Classification : Class 4
Serial No : A779

Laser

Manufacturer: Nidex
System: YC 1600 Nd:Yag
Classification: Class 3b
Serial No: 60952

Authorised Users for Class 4 Laser

Professor Jonathan Moore
Mr Andrew Spence

Laser Protection Advisor (LPA)

Simon Wharmby

Laser Protection Supervisor (LPS)

Mr Andrew Spence

Types of Treatment Provided

Refractive eye laser and other vision correction treatments carried out:

- Lasek
- Lasik
- Cross-Linking
- Presbymax

Cathedral Eye Clinic is registered as an independent hospital with the AH(DS) and PT(L) categories of registration

4.0 Summary of Inspection

An announced inspection was undertaken by Jo Browne on 13 February 2015 from 14.00 to 17.30, accompanied by Dr Ian Gillan (Medical Physics Advisor). 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 two requirements and one recommendations made as a result of the previous annual announced inspection on 14 February 2014. One requirement and one recommendation were fully addressed. One requirement had not been fully addressed and is restated within this report.

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

Mrs McCrory was available during the inspection and for verbal feedback at the conclusion of the inspection. Professor Moore was unable to attend 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 systems in place to obtain the views of patients on a formal and informal basis. The inspector reviewed the summary report of the completed patient feedback questionnaires and found that patients were highly satisfied with the care and treatment provided. Some of the comments received can be viewed in the main body of the report. Cathedral Eye Clinic collates the information from the questionnaires into a summary report which is made available to patients and other interested parties in the reception area of the establishment.

Cathedral Eye Clinic has a complaints policy and procedure in place which was found to be line with the DHSSPS guidance and legislation. No complaints have been received by the establishment, however systems are in place to effectively document, manage and audit complaints. The clinic manager displayed a good understanding of complaints management.

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

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. No incidents have been recorded by the establishment however systems are in place to document and manage and report incidents in line with the legislation.

The inspector reviewed the policy and procedures in relation to the absence of the registered manager and whistleblowing. A recommendation was made to further develop the absence of the registered manager policy to include reporting arrangements to RQIA, in line with the legislation.

The registered person/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 authorised users and found them to contain all of the information required by legislation. The medical practitioner was appropriately qualified to provide the laser refractive eye surgery services within the establishment.

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.

A number of issues were identified during the inspection in relation to the lasers and laser safety. These are detailed in full within Standard 48 of the report; requirements and recommendations were made accordingly.

The inspector reviewed six 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 post-operative 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.

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. A requirement was made to ensure that other staff working in the establishment, but not directly involved in the use of laser equipment, receive laser safety awareness training on an annual basis.

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

A requirement was made to display laser safety warning signs when the laser equipment is in use. The laser equipment is operated using keys. Arrangements are in place for the safe custody of the laser keys when not in use.

Systems were in place to service and maintain the Nd:Yag laser in line with the manufacturers' guidance. The most recent service report was reviewed by the inspector. A requirement was made to service the Class 4 laser.

A laser safety file was in place for the Class 4 laser. A recommendation was made to include information relating to the Nd:Yag laser in the file.

The protective eyewear available in the establishment for use with the Nd:Yag laser does not comply with the European Standard EN207. It is required that this matter is discussed with the establishment's LPA and suitable eyewear obtained.

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

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

Ten requirements and four recommendations were made as a result of this inspection. These are discussed fully in the main body of the report and in the appended Quality Improvement Plan.

Due to the concerns identified in relation to laser safety a follow up inspection has been scheduled within three months to ensure all issues have been fully addressed.

The inspector would like to extend her gratitude to Mrs Clare McCrory and the staff of Cathedral Eye Clinic 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	39 (1) (2)	The registered manager must ensure that all issues relating to the use of the Nd:Yag laser are fully addressed before the laser is used to treat patients.	This requirement has not been fully addressed and is therefore stated for the second time within this report.	One	Not Compliant
2	21 (3)	The registered manager must ensure that a full service history is maintained for the laser and available for inspection.	The service history for the Schwind laser was available for inspection.	One	Compliant

No.	Minimum Standard Ref.	Recommendation	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	P2	The registered manager should clarify the action point relating to the preparation of medical treatment protocols in the LPA's risk assessment and request an amended copy to be sent to the clinic.	The clinic had undertaken a risk assessment and forwarded this to the LPA. The LPA signed off this risk assessment.	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**

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 55 were returned and completed. The inspector reviewed the summary report of the completed questionnaires and found that patients were highly satisfied with the quality of treatment, information and care received. Comments from patients included:

- "The staff were very professional and helpful"
- "Staff very courteous and helpful. A credit to their profession"
- "Very impressed with staff and hospital"
- "Service very quick and friendly"
- "Quick and prompt service. Good explanation of issues and treatments"
- "Very good and professional"

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 feedback questionnaires is collated into an annual summary report which is made available to patients and other interested parties to read in the reception area of the establishment.

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 the clinic manager
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 clinic 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 found that no complaints had been received by the establishment; however systems are in place to effectively document and manage complaints.

The clinic manager confirmed that complaints would be audited as part of the establishment's clinical governance arrangements and the information would be used to identify trends and enhance services provided.

Evidenced by:

Review of complaints procedure
Complaint procedure made available to patients and other interested parties
Discussion with the clinic manager
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 provider/manager ensures the establishment delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards.

Discussion with the clinic 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:

- Infection Prevention and Control Audit
- Consent form audit
- Diagnosis audit

The registered provider/manager is involved in the day to day running of the establishment.

Systems are in place to ensure that the quality of services provided by the establishment is evaluated 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 re-admissions to establishment
- 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. No incidents have occurred within the establishment since registration; however systems are in place to document and manage incidents appropriately.

The clinic manager confirmed that audits of incidents would be undertaken (where applicable) and learning outcomes are identified and disseminated throughout the organisation.

The clinic manager confirmed that no research is currently being undertaken within the establishment. The clinic manager also confirmed before any research involving patients would be considered a research proposal would be prepared and approval obtained from the appropriate Research Ethics Committee (REC).

Evidenced by:

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

STANDARD 16	
Management and Control of Operations:	**Management systems and arrangements are in place 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.

The establishment had an absence of the registered manager policy in place, however this should be further developed to include reporting arrangements to RQIA in line with regulation 29 of the Independent Health Care Regulations (Northern Ireland) 2005.

Review of the training records and discussion with the clinic manager confirmed that the registered provider/manager undertakes 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.

The clinic manager confirmed that no agency staff are employed within the establishment.

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
Review of certificate of registration

STANDARD 48	
Laser and Intense Light Sources:	**Laser and intense light source procedures are carried out by appropriately trained staff in accordance with best practice.**

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 a consultant ophthalmologist in accordance with medical treatment protocols for the Class 4 laser produced by Professor Jonathan Moore.

A requirement is made to review the medical treatment protocols, at least annually, to ensure that they reflect current practice and procedures within the establishment. It is also recommended that document control is added to the medical treatment protocols to include the date of issue, date of review, name and signature of the author and version number.

The inspector reviewed the medical treatment protocol written by Professor Moore for the Nd:Yag Class 3b laser used for capsulotomies. This medical treatment protocol requires to be further developed to include the following information:

- 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

Once updated this medical treatment protocol should also have document control as stated above and be reviewed at least annually.

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 expires on 1 March 2015.

The establishment has local rules in place which were developed in 2010. When the establishment employed the services of a new LPA they did not issue new local rules. The LPA signed the existing local rules and validated them in 2013. It is required that systems are in place to review the local rules on an annual basis. Due the length of time since the local rules were issued it is recommended that current local rules are obtained from a LPA for the Class 4 laser.

The local rules should 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 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 for the Class 4 laser 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 clinic has introduced a Nd:Yag Class 3b laser for capsulotomies. A requirement is stated for the second time to ensure the following issues are addressed before treating patients:

- Ensure that the LPA for the clinic is informed that the Nd:Yag laser is being used
- Ensure that a risk assessment produced by the LPA includes the use of the Nd:Yag laser
- Ensure that local rules are produced for the Nd:Yag laser
- Ensure a list of authorised users is maintained for the Nd:Yag laser
- Ensure that all authorised users sign to state that they have read and agreed

to abide by the local rules and medical treatment protocols for the Nd:Yag laser
- Ensure a laser register is maintained for the Nd:Yag laser

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 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 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 the consultant ophthalmologist if necessary.

The establishment's LPS completed a risk assessment of the premises for the Class 4 and Nd:Yag laser on 1 March 2014 and forwarded this to the LPA for validation. It is required that a full risk assessment is completed by the LPA following a visit to the premises.

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

It is required that all other staff employed at the establishment, but not directly involved in the use of the laser equipment, receive laser safety awareness training on an annual basis and a record retained.

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.

The clinic manager was unable to locate the laser safety warning signs during the inspection. It is required that laser safety warning signs are displayed when the laser equipment is in use as described within the local rules.

It is required that arrangements are in place to ensure that 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 keys. Arrangements are in place for the safe custody of the laser keys when not in use.

The protective eyewear available in the establishment for use with the Nd:Yag laser does not comply with the European Standard EN207. It is required that this matter is discussed with the establishment's LPA and suitable eyewear obtained.

The Nd:Yag laser had been serviced on 12 August 2014. The Class 4 laser was serviced on 5 March 2013. A requirement is made to service and maintain the Class 4 laser in line with the manufacturers' guidance.

There is a laser safety file in place that contains all of the relevant information relating to the Class 4 laser equipment. It is recommended that information relating to the Nd:Yag laser is also included in the laser safety file.

Due to the issues identified in relation to laser safety a follow up inspection has been scheduled for 3 months to ensure all issues identified have been fully addressed.

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

7.0 Laser Protection Report

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

8.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Mrs Clare McCrory 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

The Regulation and Quality Improvement Authority

Quality Improvement Plan

Announced Inspection

Cathedral Eye Clinic

13 February 2015

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

The specific actions set out in the Quality Improvement Plan were discussed with Mrs Clare McCrory either during or after 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.

STATUTORY REQUIREMENTS

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

NO.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	39 (1)	The registered manager must ensure that arrangements are in place to review the medical treatment protocols at least annually to ensure that they reflect current practice and procedures within the establishment. The date of review should be recorded. **Ref: Standard 48**	One	DATE OF ISSUE # & NEXT REVIEW DATE HAS NOW BEEN ADDED TO ALL P&Ps.	Within three months and ongoing.
2	39 (1)	The registered manager must ensure that the medical treatment protocol for the Nd:Yag Class 3b Laser contains all of the information outlined in the main body of the report. **Ref: Standard 48**	One	THIS WILL BE FULLY ADDRESSED AT QA'S VISIT (30/4/15)	Within three months
3	39 (2)	The registered manager must ensure that systems are in place to review the local rules on an annual basis. **Ref: Standard 48**	One	LASER MET HAVE BEEN APPOINTED @ NO LESS THAN 1 ANNUAL VISIT.	Within three months
4	39	The registered manager must ensure that all issues relating to the use of the Nd:Yag laser are fully addressed before the laser is used to treat patients. **Ref: Standard 48**	Two	THIS HAS BEEN IMPLEMENTED.	Within three months

STATUTORY REQUIREMENTS

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

NO.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
5	25 (2) (d)	The registered manager must ensure that a full risk assessment is undertaken by the LPA following a visit to the premises. **Ref: Standard 48**	One	THIS IS TAKING PLACE 30/4/15.	Within three months
6	18 (2) (a)	The registered manager must ensure that staff employed at the establishment, but not directly involved in the use of the laser equipment, receive laser safety awareness training on an annual basis and a record retained. **Ref: Standard 48**	One	LSA TRAINING DATE IS BEING ARRANGED - DATE TBC 30/4/15.	Within three months
7	25 (2) (d)	The registered manager must ensure that laser safety warning signs are displayed when the laser equipment is in use as described within the local rules. **Ref: Standard 48**	One	OUR NEW LSA IS PROVIDING US WITH ALL RELEVANT SIGNS	Within three months

STATUTORY REQUIREMENTS

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

NO.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
8	25 (2) (d)	The registered manager must ensure that arrangements are in place to ensure that 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. **Ref: Standard 48**	One	A SPARE KEY IS NOW KEPT AT RECEPTION, AS DISCUSSED WITH JO BROWNE.	Immediately and ongoing
9	15 (2) (b)	The registered manager must ensure that the Class 4 laser is serviced and maintained in line with the manufacturers' guidance. **Ref: Standard 48**	One	WE ARE WORKING ON GETTING A DATE FOR THIS (SEE EMAILS RE NEW PREMISES.)	Within three months
10.	25 (2) (d)	The registered manager must ensure that the protective eyewear for the Nd:Yag laser is compliant with the European Standard EN207. This matter should be discussed with the establishment's LPA and suitable eyewear obtained. **Ref: Standard 48**	One	OUR NEW LPA IS AWARE OF THIS ISSUE AND IS ADVISING RE: SUITABLE EYEWEAR FOR LASER.	Immediately

RECOMMENDATIONS

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

NO.	MINIMUM STANDARD REFERENCE	RECOMMENDATIONS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	16.3	The registered manager should ensure that the absence of the registered manager policy is further developed to include reporting arrangements to RQIA in line with Regulation 29 of the Independent Health Care Regulations (Northern Ireland) 2005. **Ref: Standard 16**	One	THIS IS NOW INCLUDED IN OUR P&Ps, AS PER IHCRs.	Within three months
2	48.3	The registered manager should ensure that document control is added to the medical treatment protocols to include the date of issue, date of review, name and signature of the author and version number. **Ref: Standard 48**	One	THIS WILL BE INCLUDED IN THE NEW DOCUMENTATION.	Within three months
3	48.4	The registered manager should ensure that current local rules are obtained for the Class 4 laser. **Ref: Standard 48**	One	OUR NEW QA (LASER-MET) IS PROVIDING NEW LOCAL RULES.	Within three months
4	48.21	The registered manager should ensure that all information relating to the Nd:Yag laser is contained within the laser safety file. **Ref: Standard 48**	One	A SEPARATE FILE HAS BEEN SET UP FOR THE YAG LASER.	Within three months

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

Name of Registered Manager Completing QIP	JONATHAN E MOORE
Name of Responsible Person / Identified Responsible Person Approving QIP	JONATHAN E MOORE

QIP Position Based on Comments from Registered Persons	Yes	Inspector	Date
Response assessed by inspector as acceptable			
Further information requested from provider	✓		27/4/15

18th February 2015

Ms J Browne
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Ms Browne

Laser Protection Report

The Cathedral Eye Clinic
,York Street,
Belfast BT15 1ED

Introduction

This report summarises the main deficiencies in the Laser Protection arrangements which were noted during the inspection visit on 13th February 2015. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Deficiencies / Comments

Laser Safety File

The clinics laser safety documentation should be reviewed and updated. To assist in this process guidance should be obtained from a Laser Protection Adviser.

In particular the clinic should ensure that the following documents are in place for each laser system

(i) Risk assessment
(ii) Local Rules
(iii) Treatment Protocols
(iv) Letter of appointment of Laser Protection Adviser and copy of LPA's certificate
(v) Records of maintenance and service (or for new systems a copy of the manufacturer's warranty cover)

Protective Eyewear for YAG laser

The protective eyewear available in the clinic does not comply with the European Standard EN207. The clinic must discuss this matter with their Laser Protection Adviser.

The clinic should address the above deficiencies as soon as possible and contact RQIA when the matters have been addressed.

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Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Laser Systems

The Cathedral Eye Clinic, York Street, Belfast BT15 1ED

Excimer Laser

Manufacturer:	Schwind-Amaris
Serial Number:	A779
Output wavelength:	ArF (193nm)
Laser Class:	4

YAG Photo disrupter

Manufacturer:	NIDEX
Serial Number:	60952
Output wavelength:	1064nm
Laser Class:	3B

Laser Protection Advisor

Mr Simon Wharmby, Lasersafe

The Regulation and Quality Improvement Authority

Pre-Inspection Self-Assessment
Laser Refractive Eye Surgery

Name of Establishment:	**Cathedral Eye Clinic**
Establishment ID No:	**10702**
Date of Inspection:	**~~6~~ 13 February 2015**
Inspector's Name:	**Jo Browne**
Inspection No:	**18591**

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 self-assessment.

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?		✓
Have any changes been made to the management structure of the establishment since the previous inspection?		✓
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?	✓	
Are the policies and procedures for all operational areas in line with legislation and best practice guidelines?	✓	
Do all policies and procedures contain the date of issue, date of review and version control?	✓	
Are all policies and procedures ratified by the registered person?	✓	
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?	✓	
Are care records maintained for each individual patient?	✓	
Do the care records reflect the patient pathway from referral to discharge?	✓	
Are arrangements in place to securely store patient care records?	✓	
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?		
Does the establishment make available a summary report of client feedback to patients and other interested parties?		
No, please comment		

Medical Emergencies

	YES	NO
Are arrangements in place to deal with medical emergencies?		
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?		
Are all complaints documented, fully investigated and have outcomes recorded in line with the legislation and the establishment's complaints policy and procedure?		
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?	✓	
Are all incidents reported, documented, fully investigated and have outcomes recorded in line the legislation, RQIA guidance and the establishment's policy and procedure?	✓	
No, please comment		

Infection Prevention and Control

	YES	NO
Does the establishment have an infection prevention and control policy and procedure in place?	✓	
Are appropriate arrangements in place to decontaminate equipment between patients?	N/A	
Does the establishment use single use surgical instruments?	✓	
No, please comment ALL INSTRUMENTS ARE DISPOSAL / SINGLE USE.		

Recruitment of staff

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

Mandatory Training

	YES	NO
Are arrangements In place for all new authorised users to participate in an induction programme?	✓	
Are arrangements in place for medical practitioners and nurses to access continuing professional development opportunities in line with the requirements of their professional bodies?	✓	
Are training records available which confirm that the following mandatory training has been undertaken:		
AUTHORISED USERS	**YES**	**NO**
Core of knowledge training – within the past 5 year years	✓	
Application training for all equipment and all laser/IPL treatments provided - within the past 5 years	✓	
Infection prevention and control training – annually	✓	
Fire safety – annually	✓	
Basic life support – annually or valid certificate e.g. First Aid at Work which is valid for 3 years	✓	
OTHER STAFF – NOT INVOLVED IN LASER/IPL SERVICES (If applicable)	**YES**	**NO**
Laser safety awareness training – annually	✓	
If No, please comment		

Appraisal

	YES	NO
Does the establishment have an appraisal policy and procedure in place?	✓	
Are systems in place to provide recorded annual appraisals for authorised users? (if applicable)	✓	
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?	✓	
Are policies and procedures in place to grant, review and withdraw practising privilege agreements for medical practitioners?	✓	
Are practising privileges agreements in place for all medical practitioners? (where applicable)	✓	
Are systems in place to ensure that medical practitioners have up to date professional indemnity insurance?	✓	
Are systems in place to ensure that medical practitioners have an annual appraisal undertaken with a trained medical appraiser?	✓	
Are arrangements in place to ensure medical practitioners have a responsible officer?	✓	
No, please comment		

Lasers/IPL Service

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

Does the establishment have a laser/IPL register(s) in place?	—	
No, please comment		

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
J E MOORE		REGISTERED MANAGER	9/2/15.