Cathedral Eye Clinic
RQIA ID: 10705
University of Ulster
York Street
Belfast
BT15 1ED

Inspector: Jo Browne
Inspection ID: IN022898

Tel: 028 9032 2020

Variation Care Inspection of Cathedral Eye Clinic

13 August 2015

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1.0 General Information

Name of establishment:	Cathedral Eye Clinic
Current Registered Address:	University of Ulster York Street Belfast BT15 1ED
Address of New Premises:	89-91 Academy Street Belfast BT1 2LS
Telephone number:	028 9032 2020
Registered Organisation/Registered Provider:	Cathedral Eye Clinic Professor Jonathon Moore
Registered Manager:	Professor Jonathon Moore
Person-in-charge of the establishment at the time of inspection:	Mrs Clare McCadden
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 August 2015 09.45 – 13.40
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 and this may be announced or unannounced.

3.0 Purpose of Variation Inspection

The purpose of the variation care inspection is to review the fitness of the proposed new premises to undertake refractive eye surgery services and determine compliance with:

- The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005;
- 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
- DHSPPS Minimum Care Standards for Healthcare Establishments, July 2014.

A further inspection will be undertaken to approve the use of the additional theatre which will be used for intraocular procedures.

4.0 Methods/Processes

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

- review of the submitted variation application forms and supported documentation;
- discussion with Mrs Clare McCadden, clinic manager;
- discussion with staff;
- assessment of the environment;
- review of documentation required by legislation and good practice; and
- evaluation and feedback.

5.0 Profile of the Establishment

The proposed new premises for Cathedral Eye Clinic are within a commercial building converted for use as refractive eye surgery establishment.

The establishment is located over three floors. The ground floor comprises of a reception area/waiting areas, four consultation rooms and one diagnostic area, offices and toilet facilities. The first floor offers three further consultation rooms, a laser treatment room, kitchen, stores, toilets and large administration suite. The second floor comprises of a pre-operative consultation area, laser suite, theatre, scrub room, post-operative recovery area, staff changing facilities, storage areas, decontamination room/dirty utility, clean utility and plant rooms.

Public car parking is available close by for patients to use.

The establishment is accessible for clients with a disability.

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

Application has been submitted to the RQIA to vary the current address of the premises of the independent hospital providing Prescribed Techniques and Technologies. This inspection will only review the refractive eye surgery service.

Laser Equipment Currently Installed in Academy Street

Ophthalmic Laser

Manufacturer:	Zeiss
Model:	VISUMAX
Serial Number:	1048412
Laser Class:	Class 3b
Output Wavelength:	1043nm

YAG Photo disrupter

Manufacturer:	NIDEX
Model:	YC 1600 Nd:Yag
Serial Number:	60952
Laser Class:	3B
Output wavelength:	1064nm

The following two lasers will be installed in the new Academy Street premises during September 2015.

Excimer Laser

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

Ophthalmic Laser

Manufacturer:	Lumenis
Model:	Selecta II SLT
Serial Number:	51883
Laser Class:	Class 3b
Output wavelength:	532nm

Laser Protection Advisor (LPA) - Dr Anna Bass (Lasermet)

Medical Support Services - Professor Jonathan Moore

Laser Protection Supervisor (LPS) - Mr Andrew Spence

Authorised Users - Professor Jonathan Moore – All laser equipment
Mr Andrew Spence – Schwind- Amaris Class 4 Laser
Mr Colin Willoughby - Lumenis Selecta II SLT Class 3b Laser

Type of Treatments Provided:

Refractive eye laser and other vision correction treatments:

- LASEK
- LASIK
- Cross-Linking
- Presbymax
- VISUMAX SMILE
- SLT Laser treatments
- Transepi PTK
- Capsulotomies
- Glaucoma

6.0 Summary

A variation application was submitted to RQIA by Professor Jonathan Moore in respect of Cathedral Eye Clinic to move from their existing premises in York Street, Belfast to new premises in Academy Street in Belfast. This inspection will only review the proposed refractive eye surgery service at the new premises. There is a theatre available for intraocular surgical procedures which will be approved under separate cover at a subsequent inspection.

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

The inspection was carried out by Jo Browne on 13 August 2015 between the hours of 09.54 and 13.40. Dr Ian Gillan, Medical Physics Expert for RQIA, was also in attendance and a copy of his report is appended to this report. An estates inspection was also undertaken at the same time and will be reported and followed up under separate cover by the estates inspector.

Ms Clare McCadden, clinic manager, was available during the inspection and for verbal feedback at the conclusion of the inspection.

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

A Statement of Purpose and Patient Guide were in place. Advice was given regarding the content of the Statement of Purpose and a recommendation made regarding the information within the Patient Guide.

Robust systems are in place to obtain the views of patients on the quality of care and treatment provided.

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

A review of training records during the previous inspection on 1 July 2015 confirmed that authorised users completed the required mandatory training. Staff not involved in the use of the lasers had received laser safety awareness training. Further additional training for the new lasers has been organised for September 2015 and will be reviewed at the subsequent follow up inspection.

There was a policy and procedure in place for infection prevention and control. The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor. The establishment had an IPC audit undertaken in August and it is required that all recommendations from this audit along with the other IPC issues identified in the main body of the report are fully addressed.

The treatment to be provided, fees, risks, complications and expected outcomes are discussed with the client during the initial consultation. Written aftercare instructions are provided following treatment.

The establishment has existing patient care records in place which will transfer over to the new premises.

The establishment has medical treatment protocols in place written by Professor Moore on 15 June 2015. A requirement was made to develop medical treatment protocols for the Lumenis SLT laser and the Zeiss VISUMAX Laser.

The establishment has local rules developed by their LPA and written on 14 July 2015. Recommendations were made to discuss the controlled area for the laser suite, locking of laser room doors, plume extractors and toxic gas hoods with the LPA and action any advice given.

A risk assessment of the premises was undertaken by the LPA and it is required that all issues identified are fully addressed.

There was list of authorised users in place for each laser.

Laser registers were in place for the Schwind laser and Nidex Nd:Yag laser. A requirement was made regarding the development of laser registers for each laser used.

Protective eyewear had been ordered as advised by the LPA in line with the local rules.

A requirement was made to ensure that laser safety warning signs are displayed outside the laser treatment room and laser suite when the lasers are in use and removed when not in use.

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

Advice was provided during the inspection regarding the management of medicines and medical emergencies.

A further follow up inspection will be scheduled in September 2015 to review the issues identified during this inspection.

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

7.0 Inspection Findings

7.1 Statement of purpose

A statement of purpose was prepared in a recognised format which covered the key areas and themes outlined in regulation 7, schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. The inspector advised that additional information included within the Statement of Purpose should be included as appendices.

7.2 Patient Guide

A Patient Guide was prepared in a recognised format which covered the key areas and themes specified in regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005. It is recommended that the Patient Guide is updated regarding the details of the registered manager, treatments available, price lists and remove the references to the IPL/Laser Skin treatments.

7.3 Patient Partnerships

The establishment already has systems in place to obtain the views of patients on the quality of treatment, information and care received using patient feedback questionnaires.

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

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

7.4 Complaints

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

Systems are in place to effectively document and manage complaints.

7.5 Staff Training and Development and Training for Staff using Lasers and Intense Light Sources

A record of training for Professor Moore and Mr Spence was reviewed during the previous follow up care inspection on 1 July 2015 and found to be up to date. The training records for the additional laser equipment will be reviewed after the equipment is installed and prior to the variation application being approved.

Core of knowledge training has been undertaken along with the safe use and application of the lasers. Further application training has been scheduled for September 2015.

All mandatory training outlined in the RQIA guidance had been completed for Professor Moore and Mr Spence. The training records for any additional authorised users will be reviewed once the lasers have been commissioned.

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

7.6 Infection Prevention and Control (IPC)

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

The establishment has employed the services of IPC expert who undertook an IPC audit on 11 August 2015. An action plan was drawn up following the audit and it is required that all issues identified are fully addressed.

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

Staff have received training in infection prevention and control.

It is recommended that signed cleaning schedules are developed and implemented for all areas.

It also recommended that arrangements are in place to ensure that equipment is decontaminated between patient and a record retained.

The establishment had adequate hand washing facilities available within the treatment areas. There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available. The clinic manager informed the inspector that some additional wall mounted liquid soap dispensers, wall mounted toilet roll dispensers and personal protective equipment (PPE) stations had been ordered for some areas and were still waiting to be fitted. Laminated hand hygiene signs should be displayed at all hand washing facilities.

It is required that the identified toiletries are removed from the toilet areas and all cleaning products are stored in locked cupboards in line with COSSH regulations.

The clinic manager informed the inspector that sharps containers will be wall mounted and the fittings had been ordered.

7.7 Laser Procedures

The establishment has policies and procedures for advertising and marketing which are factual and not misleading. Advertisements do not offer discounts linked to a deadline for booking appointments. Promotional events do not include financial incentives for potential clients to book a consultation at the event.

Patients have an initial consultation with a fully qualified optometrist who discusses their treatment options and the cost of surgery. The establishment has a price list available for each type of treatment; 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 being undertaken.

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

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

Patients are asked to complete a health questionnaire. There are systems in place to contact the client's GP, with their consent, for further information if necessary.

7.8 Procedures for the User of Lasers and Intense Light Sources

Refractive eye surgical procedures using the Schwind Laser are carried out by a consultant ophthalmologist in accordance with medical treatment protocols for the produced by Professor Jonathan Moore in June 2015. Medical treatment protocols for the Nidex Class 3b Nd:Yag laser produced by Professor Jonathan Moore in June 2015 are also in place.

Systems are in place to review these medical treatment protocols every annually.

The medical treatment protocols sets out:

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

It is required that medical treatment protocols are developed for the Lumenis SLT laser and the Zeiss VISUMAX Laser and signed by Professor Moore. Currently the establishment has copies of the protocols produced by the manufacturer.

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

The establishment has local rules in place for each laser which have been developed by their LPA on 14 July 2014.

Systems are in place to review the local rules annually.

A risk assessment of the premises was undertaken on 14 July 2015 by the LPA.
The inspector advised that the LPA should visit the premises once all lasers have been commissioned to complete a final review of laser safety protection. All recommendations made by the LPA should be addressed.

The local rules cover:

- The potential hazards associated with lasers and intense light sources
- Controlled and safe access
- Authorised operators' responsibilities
- Methods of safe working
- Safety Checks
- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incident procedures

The local rules for the VISUMAX laser refers to the use of a plume extractor; it is recommended that this is discussed with the establishment's LPA and addressed as necessary.

The local rules for the Schwind Laser refers to the use of a toxic gas protective hood. It is also recommended that this is discussed with the establishment's LPA and addressed as necessary.

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

Laser operators are authorised to use the equipment and a register of authorised users is maintained for each piece of equipment.

Authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

A register should be maintained for every time each laser is operated and should include:

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

Laser registers were in place for the Schwind and Nidex lasers. It is required that laser registers are established for the VISUMAX and Lumenis SLT laser in line with the legislation.

The establishment has existing patient care records in place which will transfer over to the new premises. The care records were reviewed at the previous inspection on 13 February 2015 and found to be well completed, contained the relevant health questionnaire, signed consent form and record of treatment provided.

7.9 Safe Operation of Lasers and Intense Light Sources

The Lumenis SLT and the Nidex Nd:Yag lasers will be operated within the laser treatment room on the first floor of the premises. The environment in which the lasers are used was found to be 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.

The Schwind and VISUMAX lasers will be operated within the laser suite on the second floor of the premises. There was some confusion during the inspection regarding the demarcation of the controlled area surrounding these lasers, in particular in relation to the scrub/prep room. It is recommended that the controlled area is further discussed with the LPA and the controlled area clarified.

The laser safety warning signs had not been fitted at the time of inspection outside the laser treatment room or laser suite. It is required that laser safety warning signs are displayed when lasers are in use and removed when not in use as described within the local rules.

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

The clinic manager confirmed that protective eyewear has been ordered for as outlined in the local rules by their LPA.

The arrangements for locking the doors to the laser treatment room and the laser suite where discussed. Further action is required to ensure that the doors to both areas can be locked when the lasers are in use and opened easily from the outside in the event of an emergency. Arrangements should be discussed and agreed with the establishment's LPA.

There are formal written arrangements in place for the safe custody of the laser keys.

There is a laser safety file in place.

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

8.0 Medication

Advice was given during the inspection regarding the storage of eye drops and other medication.

9.0 Management of Medical Emergencies

Advice was given regarding the equipment required for the management of medical emergencies. The clinic manager was directed to the Resuscitation Council (UK) guidelines.

10.0 Laser Protection Report

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

11.0 Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Mrs Clare McCadden, clinic manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained within the QIP 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.

11.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered person meets legislative requirements based on 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.

11.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments. They promote current good practice and if adopted by the registered person may enhance service, quality and delivery.

11.3 Actions Taken by the Registered Manager/Registered Person

The QIP should be completed by the registered person/registered manager and detail the actions taken to meet the legislative requirements stated. The registered person will review and approve the QIP to confirm that these actions have been completed. Once fully completed, the QIP will be returned to independent.healthcare@rqia.org.uk and assessed by the inspector.

Quality Improvement Plan	
Statutory Requirements	
Requirement 1 **Ref:** Regulation 15 (7) **Stated:** First time **To be Completed by:** **13 September 2015**	The registered person must ensure that all issues identified within the IPC audit are fully addressed.
	Response by Registered Person(s) Detailing the Actions Taken:
Requirement 2 **Ref:** Regulation 25 (2) (d) **Stated:** First time **To be Completed by:** **13 August 2015**	The registered person must ensure that the identified toiletries are removed from the toilet areas and all cleaning products are stored in locked cupboards in line with COSSH regulations.
	Response by Registered Person(s) Detailing the Actions Taken:
Requirement 3 **Ref:** Regulation 39 (1) **Stated:** First time **To be Completed by:** **13 September 2015**	The registered person must ensure that medical treatment protocols are developed for the Lumenis SLT laser and the Zeiss VISUMAX Laser, dated and signed by Professor Moore.
	Response by Registered Person(s) Detailing the Actions Taken:
Requirement 4 **Ref:** Regulation 39 **Stated:** First time **To be Completed by:** **13 September 2015**	The registered person must ensure that all issues identified by the LPA are fully addressed.
	Response by Registered Person(s) Detailing the Actions Taken:

Requirement 5 **Ref:** Regulation 21 (3) Schedule 3 Part II (3) **Stated:** First time **To be Completed by: 13 September 2015**	The registered person must ensure that laser registers are established for the VISUMAX and Lumenis SLT lasers and contain all of the information required by legislation, as outlined in the main body of the report. **Response by Registered Person(s) Detailing the Actions Taken:**
Requirement 6 **Ref:** Regulation 25 (2) (d) **Stated:** First time **To be Completed by: 13 September 2015**	The registered person must ensure that laser safety warning signs are displayed outside the laser treatment room on the first floor and laser suite on the second floor when the lasers are in use. The signs should be removed when the lasers are not in use, in line with the local rules. **Response by Registered Person(s) Detailing the Actions Taken:**
Requirement 7 **Ref:** Regulation 25 (2) (d) **Stated:** First time **To be Completed by: 13 September 2015**	The registered person must ensure that the doors to the laser treatment room and laser suite can be locked when the lasers are in use and opened easily from the outside in the event of an emergency. Arrangements should be discussed and agreed with the establishment's LPA. **Response by Registered Person(s) Detailing the Actions Taken:**
Recommendations	
Recommendation 1 **Ref**: Standard 1.3 **Stated:** First time **To be Completed by: 13 September 2015**	It is recommended that the Patient Guide is updated as outlined in in the main body of the report. **Response by Registered Person(s) Detailing the Actions Taken:**
Recommendation 2 **Ref**: Standard 20.2 **Stated:** First time **To be Completed by: 13 September 2015**	It is recommended that signed cleaning schedules are implemented for all areas. **Response by Registered Person(s) Detailing the Actions Taken:**

Recommendation 3 **Ref**: Standard 21.4 **Stated:** First time **To be Completed by:** **13 September 2015**	It is recommended that arrangements are in place for the decontamination of all reusable medical devices and a record retained.
	Response by Registered Person(s) Detailing the Actions Taken:
Recommendation 4 **Ref**: Standard 48.3 **Stated:** First time **To be Completed by:** **13 September 2015**	It is recommended that the use of a plume extractor, as outlined in the local rules for the VISUMAX laser, is discussed with the LPA and addressed, as necessary.
	Response by Registered Person(s) Detailing the Actions Taken:
Recommendation 5 **Ref**: Standard 48.3 **Stated:** First time **To be Completed by:** **13 September 2015**	It is recommended that the use of a toxic gas protective hood, as outlined in the local rules for the Schwind laser, is discussed with the LPA and addressed, as necessary.
	Response by Registered Person(s) Detailing the Actions Taken:
Recommendation 6 **Ref**: Standard 48.14 **Stated:** First time **To be Completed by:** **13 September 2015**	It is recommended that the controlled area surrounding the second floor laser suite is further discussed with the LPA and clarification sought around the demarcation of this area.
	Response by Registered Person(s) Detailing the Actions Taken:

Registered Manager Completing QIP		**Date Completed**	
Registered Person Approving QIP		**Date Approved**	
RQIA Inspector Assessing Response		**Date Approved**	

Please ensure the QIP is completed in full and returned to Independent.Healthcare@rqia.org.uk from the authorised email address*