Cathedral Eye Clinic
RQIA ID: 12178
89 - 91 Academy Street
Belfast
BT1 2LS

Inspector: Winnie Maguire
Inspection ID: IN022939

Tel: 028 9032 2020

Announced Follow Up Variation to Registration Inspection of Cathedral Eye Clinic

23 September 2015

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1. Summary of Inspection

An announced follow up variation inspection took place on 23 September 2015 from 13.15 to 16.45. Overall on the day of the inspection the establishment was found to be generally delivering safe, effective and compassionate care. The outcome of the inspection was the Zeiss Visumax and Schwind-Amaris lasers were approved for use however a number of issues arose regarding the provision of cataract surgery and the use of the Lumenis SLT laser and these components of the service were not approved for use.

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 (DHSPPS) Minimum Care Standards for Healthcare Establishments 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	1	1

The details of the QIP within this report were discussed with Professor Jonathan Moore, registered provider and Sheena Maxwell, registered manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/Registered Person: Jonathan Moore	**Registered Manager:** Sheena Judith Maxwell
Person in Charge of the Establishment at the Time of Inspection: Jonathan Moore	**Date Manager Registered:** 28 September 2015
Categories of Care: AH(DS) – Acute Hospital (day surgery only) PT(L) - Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers	

Laser equipment

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

Excimer Laser

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

The laser below has not yet been installed.

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)

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 (pending authorisation)

Medical Support Services: Professor Jonathan Moore

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

3. Inspection Focus

The purpose of this follow up variation inspection was to review the action taken to address the issues raised during the previous announced variation inspection on 23 July 2015 and review the proposed cataract surgery service.

4. Methods/Process

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

During the inspection the inspector met with Professor Jonathan Moore, registered provider, Sheena Maxwell, registered manager, Pat Killough, theatre sister and Julie McKegney, office manager.

The following records were examined during the inspection:

- Laser safety file
- Laser risk assessment
- Policies and procedures
- Training records
- Local rules
- Medical treatment protocols
- Equipment service records

5. The Inspection

5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced pre-registration care inspection dated 23 July 2015. The quality improvement plan (QIP) from that inspection has been reviewed as part of this inspection dated 23 September 2015.

5.2 Review of Requirements and Recommendations from the Last Variation Care Inspection dated 23 July 2015

Previous Inspection Statutory Requirements		Validation of Compliance
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.	**Met**
	Action taken as confirmed during the inspection: Review of individual recommendations outlined in the IPC audit and the associated action plan found all had been addressed.	
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.	**Met**
	Action taken as confirmed during the inspection: Review of the facilities found all cleaning products are stored in line with COSSH regulations. There were no unattended toiletries observed.	
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.	**Partially Met**
	Action taken as confirmed during the inspection: Dated and signed medical treatment protocols were in place for the Zeiss VISUMAX laser. The inspector was informed the Lumenis SLT laser was not on the premises and no medical treatment protocols or other relevant documentation was available for this laser. A further inspection will be conducted to review the use of the Lumenis SLT laser.	

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.	**Met**
	Action taken as confirmed during the inspection: All areas have been addressed following further advice and clarification from the LPA.	
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.	**Met**
	Action taken as confirmed during the inspection: Laser registers have been established which contain all of the information required by legislation.	
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.	**Met**
	Action taken as confirmed during the inspection: Laser warning signs are displayed outside the laser treatment room on the first floor and laser suite on the second floor when lasers are in use. Staff confirmed the laser warning signs are removed when lasers not in use, in line with local rules.	

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.	**Met**
	Action taken as confirmed during the inspection: Arrangements to ensure doors can be locked when lasers are in use and opened easily from the outside in the event of an emergency are in place. This includes break glass boxes with an emergency key outside laser room doors. An engineer's report was forwarded following inspection confirming controlled access regarding the glass sliding door leading to the laser suite on the second floor.	
Previous Inspection Recommendations		**Validation of Compliance**
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.	**Met**
	Action taken as confirmed during the inspection: Review of the patient guide found it to be in line with legislation following further minor amendments carried out on inspection.	
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.	**Met**
	Action taken as confirmed during the inspection: Cleaning schedules were in place; advice was given on further development and amendments were made on inspection in line with this advice.	

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.	**Not Met**
	Action taken as confirmed during the inspection: Management stated arrangements have yet to be confirmed formally regarding the decontamination of all reusable medical instruments. There was no documentary evidence available outlining the contractual arrangements for the provision of an accredited decontamination service for reusable medical instruments. Management were aware without evidence of formal arrangements in place on this matter the provision of cataract surgery would not be approved.	
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.	**Met**
	Action taken as confirmed during the inspection: The use of the plume extractor has been removed from the local rules following consultation with the LPA.	
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.	**Met**
	Action taken as confirmed during the inspection: The use of a toxic gas protective hood has been removed from the local rules following consultation with the LPA. It was confirmed the machine is a sealed unit.	

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.	**Met**
	Action taken as confirmed during the inspection: The controlled area had been discussed with the LPA and a basic floor plan outlined the demarcation of the controlled area. On examination this area remained unclear and confirmation from the LPA was informal. Following inspection further documentary evidence was provided which clearly outlined the demarcation of the controlled area and formal written approval by the LPA.	

5.3 Other Areas Reviewed

Lumenis SLT laser

On discussion it was confirmed the Lumenis SLT laser was not on site and medical treatment protocols were not available. The authorised user of this laser is viewed as a private doctor under the Independent Health Care Regulations NI 2005 and the private doctor category of care variation of registration process has not been completed.

A further visit will be undertaken regarding the use of this laser and it is not approved for use as a result of the inspection undertaken on 23 September 2015.

Proposed Cataract Surgery Service

A review of the proposed cataract surgery service was undertaken. Through discussion with management and staff, observation of the theatre suite and review of relevant documents, the following was noted:

- arrangements to provide suitably qualified and skilled staff was confirmed with management;
- the IPC audit had included the theatre suite area and all areas had been actioned;
- microbiological studies had been undertaken;
- the emergency trolley was reviewed and it was advised emergency equipment should be in place as recommended in Resuscitation Council (UK) guidelines. Photographic evidence was provided following the inspection confirming emergency equipment was in line with Resuscitation Council (UK) guidelines;
- the patient call bell system was limited and advice was given to enhance the provision;
- documentary evidence was provided following inspection confirming additional patient call bell devices had been installed together with a centralised alert panel;
- management confirmed single use surgical instruments were in use with minimum use of reusable surgical instruments; and

- management stated as outlined above the arrangements for decontamination of reusable medical devices had yet to be confirmed formally. Evidence of formal arrangements must be in place.

The cataract surgery service has not been approved for use as a result of the inspection dated 23 September 2015. Documentary evidence of formal arrangements for the decontamination of reusable medical instruments must be forwarded to RQIA.

6.0 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**.**

7.0 Conclusion

As result of this inspection and following consultation with Lynn long senior inspector RQIA, the use of the Zeiss VISUMAX and Schwind–Amaris lasers has been approved.

The provision of a cataract surgery service has not been approved. The recommendations outlined in the quality improvement plan should be addressed. In addition any issues identified by RQIA's estates inspector as a result of the visit undertaken on 23 September 2015 should be addressed. Further consideration will be given to approval on receipt of the above.

The Lumensi SLT laser was not on site and as outlined previously the use of this laser is not approved and a further inspection will be conducted.

8.0 Quality Improvement Plan

The issue identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Professor Jonathan Moore, registered provider and Sheena Maxwell, registered 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.

8.1 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, and The Independent Health Care Regulations (Northern Ireland) 2005.

8.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The DHSSPS Minimum Care Standards for Independent Healthcare Establishments, July 2014. They promote current good practice and if adopted by the registered person/s may enhance service, quality and delivery.

8.3 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.

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 practice. 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(s) from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person(s) with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the practice.

Quality Improvement Plan

Statutory Requirements

Requirement 1 **Ref**: Regulation 39(1) **Stated: Second time** **To be Completed by:** 28 November 2015	The registered person must ensure medical treatment protocols are developed for the Lumenis SLT laser. **Response by Registered Person(s) Detailing the Actions Taken:** AGREEMENT PROTOCOLS ARE ALREADY DEVELOPED & SIGNED BY PROF MOORE.

Recommendations

Recommendation 1 **Ref**: Standard 21.4 **Stated: Second time** **To be Completed by:** 28 October 2015	It is recommended that arrangements are in place for the decontamination of all reusable medical devices and a record retained. Formal documentary evidence of these arrangements should be provided to RQIA. **Response by Registered Person(s) Detailing the Actions Taken:** WE ARE STILL AWAITING RECEIPT OF THE CONTRACT & WILL FORWARD TO RQIA ASAP.

Registered Manager Completing QIP	[signature]	**Date Completed**	16/10/15
Registered Person Approving QIP	JE MOORE.	**Date Approved**	16/10/15
RQIA Inspector Assessing Response	[signature]	**Date Approved**	21/10/15

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