Unannounced Enforcement Compliance Inspection Report

11 May 2016

Laserway Laser Clinic

Address: 82 Lower Mill Street, Ballymena, BT43 5AF
Tel No: 028 2563 8209
Inspector: Stephen O'Connor and Lynn Long

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

1. Summary of Inspection

An unannounced enforcement compliance inspection took place on 11 May 2016 from 10:00 to 11:25.

The purpose of the inspection was to assess the level of compliance achieved in relation to a failure to comply (FTC) notice, FTC/IHC-PT(L)-PT(IL)11990/2015-16/01, issued on 17 February 2016. The date for compliance with the notice issued on 17 February 2016 was 23 March 2016. At the request of Ms Imelda Barrett, registered person, the compliance inspection was brought forward to an earlier date and carried out on 18 March 2016. The compliance inspection on 18 March 2016 identified that compliance had not been achieved. As some progress had been made a decision was made to extend the compliance date to 11 May 2016. The areas for improvement and compliance with regulation were in relation to laser and intense pulse light (IPL) safety.

FTC Ref: FTC/IHC-PT(L)-PT(IL)/11990/2015-16/01

Evidence was available to confirm that systems and processes have been implemented to address the deficits identified with laser and IPL safety. Inspectors were satisfied that full compliance had been achieved with the above failure to comply notice.

The actions to be taken by the registered person as outlined in the failure to comply notice included ensuring that the protective eyewear was of the same level of protection as outlined in the local rules and that the laser protection file was reviewed to ensure it was up to date. It was identified that the protective eyewear and the medical treatments protocols for the Erbium Alma Harmony laser were not available. Review of documentation and discussion with Ms Barrett and staff demonstrated that the issues in respect of the Erbium laser are being progressed. It was also evidenced that robust measures had been taken to ensure this laser is not used until such times as the identified issues have been addressed. A requirement has been made in regards to the Erbium Alma Harmony laser.

1.1 Actions/Enforcement* Taken Following the Last Enforcement Monitoring Inspection

Following an announced care inspection on 10 February 2016 a failure to comply notice was issued to Laserway Laser Clinic on 17 February 2016 relating to poor practice with laser and IPL safety.

An enforcement compliance inspection was carried out on 18 March 2016 to assess compliance with the failure to comply notice. Evidence was not available at this time to validate compliance with the notice. A decision was made to extend the compliance date. The date for compliance on the extended notice was 11 May 2016.

1.2 Actions/Enforcement* Resulting From This Inspection

As indicated above, evidence was available to validate full compliance with the above failure to comply notice.

*All enforcement notices for registered agencies/services are published on RQIA's website at: http://www.rqia.org.uk/inspections/enforcement_activity.cfm

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	1	0

The details of the QIP within this report were discussed with Ms Barrett, registered person, and staff as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/Registered Person: Liteworks Limited Ms Imelda Barrett	**Registered Manager:** Ms Imelda Barrett
Person in Charge of the Home at the Time of Inspection: Ms Imelda Barrett	**Date Manager Registered:** 16 January 2014
Categories of Care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources.	

3. Inspection Focus

The inspection sought to assess the level of compliance with the required actions indicated within the failure to comply notice issued on 17 February 2016 and extended on the 18 March 2016. The date for compliance on the extended notice was 11 May 2016.

4. Methods/Process

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

- discussion with Ms Barrett, registered person
- discussion with two authorised users
- review of training records
- review of laser protection file
- observation during a tour of the premises
- evaluation and feedback

5. The Inspection

5.1 FTC Ref: FTC/IHC-PT(L)-PT(IL)/11990/2015-16/01

The Independent Health Care Regulations (Northern Ireland) 2005

39 (2) The registered person shall ensure that such a laser or intense light source is used in or for the purposes of the hospital only by a person who has undertaken appropriate training and has demonstrated an understanding of –
(a) the correct use of the equipment in question;
(b) the risks associated with using a laser or intense light source;
(c) its biological and environmental effects;
(d) precautions to be taken before and during use of a laser or intense light source

The inspection findings of the actions specified in the FTC notice are as follows:

The registered person must ensure that all recommendations made by the appointed Laser Protection Advisor (LPA) are fully addressed, signed and dated on completion by the Laser Protection Supervisor (LPS).

Review of the LPA risk assessment dated 9 March 2016 and additional documentation and discussion with Ms Barrett and staff demonstrated that all recommendations made by the LPA have been addressed. The LPS had signed and dated the recommendations made within the LPA risk assessment to confirm that they had been addressed.

The registered person must ensure that the protective eyewear for the laser/IPL equipment is of the same level of protection as outlined within the local rules produced by the LPA.

A Candella Lase Pro laser, an Erbium Alma Harmony laser and a Ellipse Light IPL machine are available in this establishment.

Review of the protective eyewear available for both operators and clients evidenced that the protective eyewear for the Candella Lase Pro laser and the Ellipse Light IPL machine were in keeping with the local rules.

It was confirmed that protective eyewear for the Erbium Alma Harmony laser was not available. Ms Barrett confirmed that the protective eyewear specified by the LPA in the local rules had been ordered from LPA. The appointed LPA had also confirmed to RQIA that the protective eyewear for the laser had been ordered. It was evidenced that measures had been put in place to ensure that the laser would not be used until such times at the protective eyewear was available, as detailed below:

- the laser had been removed from the treatment room
- the laser was labelled not for use
- it was clearly recorded in the establishments appointment book that treatments using the Erbium laser were not to be booked

RQIA are satisfied that robust systems have been implemented to ensure that the laser will not be operational until such times as the protective eyewear specified in the local rules is available. It was also established that medical treatments protocols for the treatments to be provided using the laser were not available. This is discussed further below. A requirement was made that the registered person must ensure the laser is not used until such times as the issues identified above have been addressed.

The registered person must ensure that the protective eyewear is maintained in accordance with the manufacturer's guidance.

Discussion with two authorised users confirmed that arrangements are in place to ensure that the protective eyewear is maintained in accordance with the manufacturer's guidance. Review of documentation demonstrated that the maintenance of protective eyewear was discussed at a staff meeting held on 27 April 2016. It was confirmed that minutes of this staff meetings had been emailed to all staff.

The registered person must ensure that robust systems are implemented to ensure that defective equipment is identified, reported and repaired/replaced as required.

A specific logbook had been established to record defective equipment and discussion with two authorised users confirmed that they had good awareness of the actions to be taken in the event of any issues being identified.

The registered person must ensure that all authorised users have complete training or update training in core of knowledge and the safe use and application of the laser/IPL equipment.

Review of documentation demonstrated that all authorised users have up-to-date core of knowledge and safe use and application training for all treatments provided using the lasers and IPL equipment.

The registered person must ensure that the training provided is embedded into practice to ensure the health and safety of clients and staff is maintained.

As discussed above all staff had up-to-date core of knowledge and safe use and application training. Discussion with staff evidenced that their level of knowledge and understanding in regards to the safe use and operation of the laser and IPL machines had improved.

The laser protection file must be reviewed to ensure it is up-to-date.

Review of the laser protection file evidenced that it had been reviewed and was up-to-date, with the exception of the medical treatment protocols for the treatments to be provided using the Erbium Alma Harmony laser. Ms Barrett confirmed that the LPA visited the establishment during March 2016 and that the medical treatment protocols for the laser have yet to be issued. As discussed previously robust measures have been implemented to ensure the laser is not used until such times as the identified issues have been addressed. A requirement has been made in respect of the laser.

6. Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Ms Barrett, registered person, and staff as part of the inspection process. The timescales commence from the date of inspection.

The registered person 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 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.

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

6.2 Recommendations

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

6.3 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 areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the registered person/manager from their responsibility for maintaining compliance with the regulations and standards. It is expected that the requirements and recommendations outlined in this report will provide the registered person/manager with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

Quality Improvement Plan

Statutory Requirements	
Requirement 1 **Ref:** Regulation 39 (1) & (2) (d) **Stated:** First time **To be Completed by:** 11 May 2016	The registered person must ensure that the Erbium Alma Harmony laser remains out of use until such times as the following issues have been addressed: • protective eyewear as specified by the LPA in the local rules for the Erbium Alma Harmony laser are available in the establishment • medical treatment protocols for each treatment to be provided using the Erbium Alma Harmony laser are available in the establishment Confirmation must be provided to RQIA that the issues identified above have been addressed prior to the Erbium Alma Harmony laser becoming operational.
	Response by Registered Person Detailing the Actions Taken: Eye wear for the alma are now on the establishment. Please see pictures attached which the LPA has approved. Medical protocols have been addressed by the LPA and are currently being processed but have not been delivered to the establishment therefore this erbium laser is not operational and will continue not to be until these arrive. I will send confirmation to you as soon as they arrive on site.

The Regulation and Quality Improvement Authority

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