

**Announced Care Inspection
of
Laserase Clinic**

18 September 2015

1. Summary of Inspection

An announced care inspection took place on 18 September 2015 from 09.45 to 12.25. Overall on the day of inspection the standards inspected were found to be generally safe, effective and compassionate. Areas for improvement were identified and are set out in the Quality Improvement Plan (QIP) within this report.

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, July 2014.

1.1 Actions/ Enforcement Taken Following the Last Care Inspection

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

1.2 Actions/ Enforcement Resulting from this Inspection

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

1.3 Inspection Outcome

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

The details of the QIP within this report were discussed with Mrs Therese McKeown, 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: Laserase Medical Skincare Clinic Mrs Therese McKeown	Registered Manager: Mrs Therese McKeown
Person in Charge of the Establishment at the Time of Inspection: Mrs Therese McKeown	Date Manager Registered: 11 April 2007
Categories of Care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers, PT(IL) prescribed techniques or prescribed technology: establishments using intense light sources and PD private doctor.	

Combine IPL & Laser

Manufacturer: ESC - Sharplan
 Model: Vasculight
 Serial Number: SA 234 7001
 Laser Class: Class 4
 Wavelength: Nd:YAG (1064nm)
 IPL: Single IPL head with interchangeable filters

Dye Laser

Manufacturer: Euphotonics
 Model: NLite – V Multifunction Laser
 Laser Class: Class 4
 Wavelength: 580nm – 590nm

Nd YAG Laser

Manufacturer: Cynosure
 Model: Affirm
 Serial Number: AFRM0037
 Laser Class: Class 4
 Wavelength: 1440nm

Nd YAG Laser

Manufacturer: Cynosure
 Model: Affinity QS
 Serial Number: QPA0470-0508
 Laser Class: Class 4a
 Wavelength: 1064nm & 532nm

IPL Equipment

Manufacturer: Lumenis
 Model: Quantum SA35011000
 Serial Number: 045-01625
 Laser Class: Single head IPL

Ruby Laser (Decommissioned)

Manufacturer: Lambada Photometrics
 Serial Number: 5653RCU 019307
 Laser Class: Class 4
 Wavelength: Ruby (694nm)

Laser Protection Advisor (LPA) - Mr Irfan Azam (Lasermet)

Laser Protection Supervisor (LPS) – Dr Donal McKeown

Medical Support Services – Dr Paul Myers (Lasermet)

Authorised Users - Dr Donal McKeown & Ms Amanda Houston

Types of Laser and IPL Treatment Provided - Hair removal, vascular lesions, acne, rosacea, tattoo removal, brown pigmentation lesions, fine lines/wrinkles, photo aging and facial flushing and erythema.

Private Doctor Treatments Provided – Botox and cosmetic fillers

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the previous inspection and to determine if the following standards have been met:

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

Other areas inspected: Incidents, insurance arrangements, private doctor service, management of sharps and RQIA registration.

4. Methods/ Process

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

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

During the inspection the inspector met with Mrs Therese McKeown, Registered Manager and one receptionist.

The following records were examined during the inspection:

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|---------------------------------|-------------------------------|
| • Six client care records | • Incident/ accident records |
| • Laser safety file | • Local rules |
| • Laser risk assessment | • Medical treatment protocols |
| • Policies and procedures | • Equipment service records |
| • Client feedback questionnaire | • Complaints records |
| • Training records | • Two personnel files |

5. The Inspection

5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 31 October 2014. The completed QIP was returned and approved by the care inspector.

5.2 Review of Requirements and Recommendations from the Last Care Inspection on 31 October 2014

Previous Inspection Statutory Requirements		Validation of Compliance
Requirement 1 Ref: Regulation 15 (2) (a) Stated: Second time	The registered provider/ manager must ensure that the protective eyewear for the laser equipment is discussed and agreed with the LPA. Copy of the confirmation of approval from the LPA for the eyewear to be used must be forwarded to RQIA.	Met
	Action taken as confirmed during the inspection: The protective eyewear was discussed with the LPA during his recent visit and new eyewear ordered as outlined in the local rules.	
Requirement 2 Ref: Regulation 18 (2) (a) Stated: First time	The registered provider/ manager must ensure that all authorised users complete the mandatory training as outlined in the main body of the report.	Partially Met
	Action taken as confirmed during the inspection: Review of the training records confirmed that the one authorised user requires an update in basic life support. This requirement is made for the second time within this report.	
Requirement 3 Ref: Regulation 39 (2) Stated: First time	The registered provider/ manager must ensure that all issues identified by the LPA are fully addressed and the list of recommendations made by the LPA are signed and dated as completed by the LPS. Ref: Standard 48	Met
	Action taken as confirmed during the inspection: Discussion with the registered manager and review of documentation confirmed that all recommendations made by the LPA had been addressed.	

Requirement 4 Ref: Regulation 9A (1) (b) Stated: First time	<p>The registered provider/ manager must ensure that policies, procedures and medical treatment protocols are developed for all other services provided by the medical practitioner.</p> <p>Action taken as confirmed during the inspection: Review of documentation confirmed that appropriate medical treatment protocols had been implemented for other services provided by the medical practitioner.</p>	Met
Requirement 5 Ref: Regulation 9 (a) Stated: First time	<p>The registered provider/ manager must ensure that Statement of Purpose and Client Guide are updated to include the provision of the private doctor service.</p> <p>Action taken as confirmed during the inspection: Review of the Statement of Purpose and Client Guide confirmed that they had been updated to include the provision of the private doctor service.</p>	
Previous Inspection Recommendations		Validation of Compliance
Recommendation 1 Ref: Standard 5.2 Stated: First time	<p>The registered provider/manager should ensure that a copy of the summary report of client feedback is made available to clients and other interested parties.</p> <p>Ref: Standard 5</p> <p>Action taken as confirmed during the inspection: The registered manager confirmed that a copy of the summary report is made available to clients and other interested parties in the waiting area of the premises.</p>	Met

Recommendation 2 Ref: Standard 48.13 Stated: First time	The registered provider/ manager should ensure that all other staff employed at the establishment, but not directly involved in the use of the IPL/ laser equipment, receives laser safety awareness training annually and a record retained. Ref: Standard 48	Met
	Action taken as confirmed during the inspection: Review of training records confirmed that all other staff employed at the establishment who are not directly involved in the use of the IPL/ laser equipment received laser safety awareness training.	

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and treatment process, with Mrs McKeown and staff confirmed that clients' modesty and dignity is respected at all times. The consultation and treatment is provided in a private room with the client and authorised user present.

Observations confirmed that client care records were stored securely in a locked filing room.

Is Care Effective?

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

Clients meet with the authorised user undertaking the treatment and are fully involved in decisions regarding their treatment. Clients' wishes are respected and acknowledged by the establishment.

Is Care Compassionate?

Discussion with staff and review of four laser/ IPL client care records and two private doctor care records confirmed that clients are treated and cared for in accordance with legislative requirements for equality and rights.

Areas for Improvement

No areas for improvement were identified during the inspection.

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

Is Care Safe?

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

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

Is Care Effective?

Laserase obtains the views of clients and/ or their representatives on a formal and informal basis as an integral part of the service they deliver.

The establishment issued feedback questionnaires to clients and 40 were returned and completed. Review of the completed questionnaires found that clients were highly satisfied with the quality of treatment, information and care received.

Some comments from clients included:

"Found clinic excellent."

"Service at Laserase is always excellent. Staff friendly and very willing to accommodate when changing appointments."

"Great clinic with very friendly staff."

"Great service and great results – would highly recommend."

"The Dr at Laserase is excellent. The results have been excellent."

The information received from the client feedback questionnaires is collated into an annual summary report which is made available to clients and other interested parties to read in the waiting area of the establishment.

It was confirmed through discussion that comments received from clients are reviewed by Mrs McKeown and an action plan is developed and implemented to address any issues identified.

Is Care Compassionate?

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

Areas for Improvement

No areas for improvement were identified during the inspection.

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

Is Care Safe?

No complaints have been recorded by the establishment since the last inspection. However, systems are in place to investigate and respond to complaints within 28 working days (in line with regulations) or if this is not possible, Mrs McKeown confirmed that complainants will be kept informed of any delays and the reason for this.

Discussion with Mrs McKeown confirmed that information from complaints would be used to improve the quality of services.

Is Care Effective?

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

A complaints questionnaire was forwarded by the Regulation and Quality Improvement Authority (RQIA) to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints no complaints have been recorded from 01 January 2014 to 31 March 2015.

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.

Mrs McKeown demonstrated a good understanding of complaints management.

The complaints procedure is displayed in the waiting room and also contained within the Client Guide; copies of which are available for clients to read.

Is Care Compassionate?

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

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

Areas for Improvement

No areas for improvement were identified during the inspection.

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

Is Care Safe?

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

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires on 16 June 2016.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers on 17 June 2015. Systems are in place to review the medical treatment protocols on an annual basis.

The medical treatment protocols set out:

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

The establishment has local rules in place which have been developed by their LPA on 21 August 2014. The LPA visited the premises on 11 September 2015 and the updated local rules had not been received at the time of inspection.

The local rules cover:

- The potential hazards associated with lasers
- Controlled and safe access
- Authorised operator's responsibilities
- Methods of safe working
- Safety checks
- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incidents procedures

The laser protection supervisor has overall responsibility for safety during laser treatments as recorded within the local rules.

A list of authorised users is maintained and authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

Clients are provided with written aftercare instructions following treatment.

The establishment's LPA completed a risk assessment of the premises on 6 August 2013 which expired on 20 August 2014. The establishment is waiting on the updated documentation following the recent visit by the LPA. All previous issues identified by the LPA had been addressed.

The authorised users have completed training in core of knowledge and the safe use and application of the laser and IPL equipment.

Review of the training records confirmed that the authorised users had also undertaken the majority of the following required mandatory training in line with RQIA guidance:

- Fire safety annually
- Infection prevention and control annually
- Basic life support annually

The basic life support training for one identified authorised user had expired in February 2015.

All other staff employed at the establishment, but not directly involved in the use of the laser and IPL equipment, had received laser safety awareness training.

The environment in which the laser and IPL 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 and IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use, as described within the local rules.

Protective eyewear is available for the client and operator as outlined in the local rules. Following the LPA's visit on 11 September 2015 new protective eyewear was ordered by the establishment in line with the local rules.

The door to the treatment rooms are locked when the laser and IPL equipment is in use but can be opened from the outside in the event of an emergency.

The laser and IPL equipment are operated using keys. Arrangements are in place for the safe custody of the laser and IPL keys when not in use.

Is Care Effective?

The establishment has a laser and IPL register, for each piece of equipment, 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

Four client care records were reviewed. There is an accurate and up to date treatment record for every client which includes:

- Client details;
- Medical history;
- Signed consent form;
- Skin assessment (where appropriate);
- Patch test (where appropriate); and
- Record of treatment delivered including number of shots and fluence settings (where appropriate).

There are arrangements in place to service and maintain the lasers and IPL equipment in line with the manufacturer's guidance. The most recent service reports were reviewed as part of the inspection process, along with the installation certificate for the new Lumenis IPL equipment.

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

Is Care Compassionate?

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have.

Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes.

The establishment has a list of fees available for each laser and IPL procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client.

Areas for Improvement

The identified authorised user must undertake an update in basic life support.

Number of Requirements:	1	Number of Recommendations:	0
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5.7 Additional Areas Examined

5.7.1 Management of Incidents

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

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

5.7.2 RQIA registration and Insurance Arrangements

Discussion with Mrs McKeown regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificate of RQIA registration was clearly displayed in the waiting room of the premises.

5.7.3 Private Doctor Service

In addition to the laser and IPL treatments provided; the establishment also offers a range of cosmetic injectable objects including Botox and fillers which are provided by Dr McKeown, who is a private doctor.

Following the last inspection medical treatment protocols were developed and implemented for treatments provided by the private doctor. The Statement of Purpose and Client Guide were also updated to reflect the treatments provided.

A range of comprehensive information is provided to clients undergoing Botox and filler treatment that clearly outlines the risks, complications and expected outcomes.

Two client files were reviewed and found to be well completed and in line with GMC Good Medical Practice.

A review of the private doctor's personnel file confirmed that it contained all of the information required by legislation.

5.7.4 Management of Sharps

The lid of one sharps container was observed not to be fully locked in place; this was addressed during the inspection. The labels of the sharps containers had not been completed on assembly and the temporary closure devices were not in operation.

Areas for Improvement

The temporary closure device on sharps containers should be in operation when the containers are not in use and the labels should be fully completed on assembly and permanent closure. The lids of the containers must be locked fully into place on assembly.

Number of Requirements	1	Number Recommendations:	0
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6. Quality Improvement Plan

The issue identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Mrs Therese McKeown, 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.

6.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered persons 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.

6.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety's (DHSPSS) Minimum Care Standards for Healthcare Establishments. 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 weaknesses that exist in the establishment. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person/manager with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the establishment.

Quality Improvement Plan			
Statutory Requirements			
Requirement 1 Ref: Regulation 18 (2) (a) Stated: Second time To be Completed by: 18 November 2015	The registered person must ensure that all authorised users complete the mandatory training as outlined in the main body of the report. Response by Registered Person(s) Detailing the Actions Taken: <i>Ammanda Hueston will be doing the Basic Life Support with AED training on December 12th.</i>		
Requirement 2 Ref: Regulation 15 (7) Stated: First time To be Completed by: 18 September 2015	The registered person must ensure that the lids of sharps containers are fully locked in place, the temporary closure device should be in operation when not in use and the labels must be fully completed on assembly and permanent closure. Response by Registered Person(s) Detailing the Actions Taken: <i>This requirement has been actioned.</i>		
Registered Manager Completing QIP	<i>Theresa McKeown</i>	Date Completed	<i>8/11/15</i>
Registered Person Approving QIP		Date Approved	
RQIA Inspector Assessing Response	<i>Jo Braine</i>	Date Approved	<i>11/11/15</i>

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