

Announced Inspection

Name of Establishment: Laserase Clinic

Establishment ID No: 10633

Date of Inspection: 31 October 2014

Inspector's Name: Jo Browne

Inspection No: 18575

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: | Laserase Clinic |
|--|---|
| Address: | 525 Antrim Road Belfast BT15 3BS |
| Telephone number: | 028 9077 7772 |
| Registered organisation/ registered provider: | Mrs Therese Bernadette McKeown |
| Registered manager: | Mrs Therese Bernadette McKeown |
| Person in charge of the establishment at the time of inspection: | Mrs Therese McKeown |
| Registration category: | PT(IL) – Prescribed techniques or prescribed technology: establishments using intense light sources. |
| | PT(L) – Prescribed techniques or prescribed technology: establishments using Class 3b or Class 4 lasers |
| | PD – Private Doctors |
| Date and time of inspection: | 31 October 2014 09.45 – 13.15 |
| Date and type of previous inspection: | Announced 14 November 2013 |
| Name of inspector: | Jo Browne |

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 clients 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 laser and intense pulse light (IPL) services, 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 registered provider/manager, Mrs Therese McKeown
- 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 client feedback questionnaires, issued by | 22 |
|--|----|
| the establishment | |

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 16 Management and Control of Operations
- Standard 48 Laser and Intense Light Sources

3.0 Profile of Service

Laserase Medical Clinic is well-established and offers a range of laser and intense pulse light (IPL) treatments.

The establishment is located in converted residential premises on the Antrim Road, Belfast and is close to local amenities and transport routes.

There is a waiting area and toilet facilities available for client use.

The establishment has the following equipment available:

IPL Equipment (Single Headed)

Manufacturer: ESC - Sharplan

Model: Epilight Serial Number: 422898045

IPL: Single IPL head with interchangeable filters

Combined IPL & Laser

Manufacturer: ESC - Sharplan Vasculight Serial Number: SA 234 7001

Output Wavelength: Nd:YAG (1064nm)

Laser Class: 4

IPL: Single IPL head with interchangeable filters

Dye Laser

Manufacturer: Euphotonics

Model: NLite - V Multifunction Laser

Output Wavelength: 580 - 590nm

Laser Class: 4

Nd YAG Laser

Manufacturer: Cynosure
Model: Affirm
Serial No: AFRM0037
Output Wavelength: 1440nm

Laser Class: 4

ND YAG Laser

Manufacturer: Cynosure
Model: Affinity QS
Serial Number: QPA0470-0508
Output Wavelength: 1064nm & 532nm

Laser Class: 4a

Ruby Laser (Not in Use)

Manufacturer: Lambada Photometrics Serial Number: 5653RCU 019307 Output Wavelength: Ruby (694nm)

Laser Class: 4

Laser Protection Advisor (LPA)

Irfan Azam (Lasermet)

Laser Protection Supervisor (LPS)

Dr Donal McKeown

Medical Support Services

Dr Paul Myers (Lasermet)

Authorised Users

Dr Donal McKeown Amanda Houston

The lasers and IPL equipment are used for the following treatments:

- Hair removal
- Vascular lesions
- Acne
- Rosacea
- Tattoo removal
- Brown pigmentation lesions
- Fine lines/wrinkles
- Photo aging
- Facial flushing and erythema

The establishment also provides a private doctor service for skin rejuvenation including botox and dermafiller injections.

Private car parking is available for clients and visitors.

The establishment is accessible for clients with a disability.

Mrs Therese McKeown has been the registered manager of the establishment since registration with RQIA on 11 April 2007.

Laserase Medical Clinic is registered as an independent hospital with PT(IL), PT(L) and PD categories of registration.

4.0 Summary of Inspection

An announced inspection was undertaken by Jo Browne on 31 October 2014 from 09.45 to 13.15. 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 two recommendations made as a result of the previous annual announced inspection on 14 November 2013. One requirement and one recommendation had not been fully addressed and are 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 McKeown, registered provider/manager was available during the inspection and for verbal feedback at the conclusion of 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 robust systems in place to obtain the views of clients on a formal and informal basis. The inspector reviewed the completed client feedback questionnaires and found that clients were highly satisfied with the care and treatment provided. Some of the comments received can be viewed in the main body of the report. Laserase collates the information from the questionnaires into a summary report; a recommendation was made to make the summary report available to clients and other interested parties.

Laserase 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. Mrs McKeown 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 discussed with Mrs McKeown other audits which could be undertaken by the establishment to monitor the quality of service provided.

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. They were found to be in line with legislation and best practice.

A Statement of Purpose and Client Guide were in place which reflected legislative and best practice guidance for the laser service. A requirement was made to include the services provided by the private medical practitioner within these documents.

The inspector reviewed the insurance arrangements for the establishment and found that current insurance policies were in place.

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

There were clear medical treatment protocols for the IPL and laser service along with local rules. Systems are in place to review the medical treatment protocols for the IPL/laser service and local rules on an annual basis. A service level agreement was in place between the establishment and the LPA.

The establishment has IPL and laser registers for each piece of equipment which are completed every time the equipment is operated. The inspector advised including the treatment given and the precise exposure within the IPL and laser registers; this information is currently documented within the care records.

Four client care records were examined and found to be generally well completed. The records contained the client's personal details, a completed health questionnaire, signed consent form, evidence of patch test and treatment provided.

A risk assessment had been undertaken by the establishment's LPA on 21 August 2014 and produced a list of recommendations which had not been signed as completed by the LPS. It is required that all issues identified by the LPA are fully addressed and are signed and dated by the LPS on completion.

Review of the training records confirmed that mandatory training was up to not fully up to date and a requirement was made to address this. A recommendation was also made to ensure that other staff working in the establishment, but not directly involved in the use of IPL and laser equipment, had received laser safety awareness training. Mrs McKeown informed the inspector that this had been discussed during a staff meeting but not formally recorded.

The environment in which the IPL and laser equipment is used was found to be safe and controlled. Protective eyewear was available for the client and operator. A requirement was made for the second time to ensure that the protective eyewear is agreed with the LPA as per the local rules.

Laser safety warning signs are displayed when the IPL and laser equipment is in use. The LPA had made a recommendation in relation to the type of laser warning signs used by the establishment and this must be addressed along with the other recommendations made the LPA.

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

Systems were in place to service and maintain the IPL and laser equipment in line with the manufacturers' guidance. The most recent service reports were reviewed by the inspector. A laser safety file was in place.

The certificate of registration was clearly displayed in the waiting room of the establishment.

As the medical practitioner working with the establishment is wholly private the services provided by this practitioner also fall under the regulation of RQIA.

The inspector discussed with the registered provider/manager the provision of private doctor services including botox and dermafillers injections and a requirement was made to ensure that medical treatment protocols, policies and procedures are developed for all other services provided by the medical practitioner.

Five requirements and two 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.

Overall, on the day of inspection, the establishment was found to be providing a safe and effective service.

The inspector would like to extend her gratitude to Mrs Therese McKeown and the staff of Laserase 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 | 15 (2) (a) | 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. | On review of the protective eyewear this requirement has not been addressed and is stated for the second time within this report. | Two | Not compliant |
| 2 | 18 (3) | The registered manager should ensure that Dr McKeown has an annual appraisal undertaken by a trained medical appraiser and the records retained for inspection. | The inspector reviewed the appraisal documentation for Dr McKeown as part of the inspection process. This requirement has been fully addressed. | Two | Compliant |

| No. | Minimum Standard Ref. | Recommendations | Action taken as confirmed during this inspection | Number of times stated | Inspector's validation of compliance |
|-----|-----------------------------|--|---|------------------------|--------------------------------------|
| 1 | P2 | The registered manager should ensure that the local rules are updated to reflect RQIA, NIAIC, HSENI and then signed by Dr McKeown. | The inspector reviewed the local rules and confirmed that they had been updated as previously recommended. This recommendation has been fully addressed. | One | Compliant |
| 2 | P4 | The registered manager should ensure that the LPS signs to confirm that each individual issue identified by the LPA within the risk assessment has been fully addressed. | On review of the LPA risk assessment this recommendation has not been addressed and is stated for the second time within a requirement in this report. | Two | Not 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 |

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

The establishment issued feedback questionnaires to clients and 22 were returned and completed. The inspector reviewed the completed questionnaires and found that clients were highly satisfied with the quality of treatment, information and care received. Comments from clients included:

- "Have always found excellent service"
- "Friendly staff at reception"
- "Couldn't recommend highly enough"
- "Found clinic excellent"
- "Service at Laserase is always excellent"
- "Staff friendly and very willing to accommodate when changing appointments"

The information received from the client feedback questionnaires is collated into an annual summary report. A recommendation was made to ensure that the summary report is made available to clients and other interested parties to read.

Evidenced by:

Review of client satisfaction surveys
Review of summary report of client satisfaction surveys
Summary report made available to clients and other interested parties
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 registered provider/manager demonstrated a good understanding of complaints management.

All clients are provided with a copy of the complaints procedure, which is contained within the Client 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.

Evidenced by:

Review of complaints procedure
Complaint procedure made available to clients and other interested parties
Discussion with clients and/or their representatives
Discussion with staff
Review of complaints records

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 registered provider/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:

Client satisfaction survey

The inspector discussed with Mrs McKeown other audits which could be undertaken by the establishment to monitor the quality of service provided. These areas included infection prevention and control, care records and medication.

The registered provider/manager is involved in the day to day running of 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 registered provider/manager confirmed that no research is currently being undertaken within the establishment.

Evidenced by:

Review of policies and procedures
Discussion with registered provider/manager
Review of monitoring reports
Review of audits
Review of incident management
Review of research arrangements

| STANDARD 16 | |
|----------------|---|
| Management and | Management systems and arrangements are in place |
| Control of | that ensure the delivery of quality treatment and care. |
| Operations: | |

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 has a policy and procedure in place to ensure that RQIA is notified if the registered manager is absence for more than 28 days. The policy includes the interim management arrangements for the establishment.

Review of the training records and discussion with the registered manager confirmed that they undertake training relevant to their role and responsibilities within the organisation.

The inspector reviewed the establishment's Client Guide and Statement of Purpose and found them to be in line with the legislation with regards to the provision of the laser and IPL services. A requirement was made in section 7.0 of this report in relation to including the services provided by the private doctor within these documents.

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 certificate of registration was clearly displayed in the waiting room of the premises.

Evidenced by:

Review of policies and procedures Review of training records Review of Client Guide Review of Statement of Purpose Review of insurance arrangements

| 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. |

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. The establishment has a list of fees available for each IPL or laser procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the treatment provided and the individual requirements of the client.

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.

Clients are provided with written information on the specific IPL or laser procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

IPL and laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers on17 June 2014. 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

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 16 June 2015.

The establishment has local rules in place which have been developed by their LPA on 21 August 2014.

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 IPL and 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.

The establishment has an IPL and laser 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

The inspector advised including the treatment given and the precise exposure within the IPL and laser registers. This information is currently recorded within the client's care records.

Four client care records were reviewed and found to contain information regarding the client's personal details, a completed health questionnaire, signed consent form, record of treatment and evidence of a patch test being undertaken.

Clients are provided with written aftercare instructions following treatment.

The establishment's LPA completed a risk assessment of the premises in 21 August 2014 and had produced a list of recommendations which had not been signed as completed by the LPS.

A review of the training records indicated that all of the required mandatory training was not up to date for both authorised users. A requirement is made to ensure that evidence of the following training is available for all authorised users:

- Core of knowledge training every 5 years
- Application training for each piece of equipment every 5 years
- Basic life support annually
- Fire safety annually
- Infection prevention and control annually

It was also recommended that all other staff employed at the establishment, but not directly involved in the use of the IPL/laser equipment, receive laser safety awareness training annually and a record retained. The inspector advised that this training could be provided by the LPS. Mrs McKeown informed the inspector that laser safety was discussed as part of the staff meetings. However no formal

evidence of training was available at the time of the inspection.

The environment in which the IPL and 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 IPL and laser 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 IPL and Laser equipment are in use and removed when not in use. The LPA had made a recommendation in relation to the type of laser warning signs used by the establishment and this must be addressed along with the other recommendations made the LPA.

Protective eyewear is available for the client and operator. The inspector reviewed the protective eyewear available as part of the inspection process. The LPA has highlighted issues for the second time relating to the protective eyewear within their report which have not been addressed. A requirement is made for the second time to ensure that the protective eyewear available 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.

A requirement is made to ensure that all issues identified by the LPA are fully addressed and it is recommended for the second time that the list of LPA recommendations are signed by the LPS to show that they have been completed.

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

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

There are arrangements in place to service and maintain the IPL and laser equipment in line with the manufacturer's guidance. The most recent service reports were reviewed as part of the inspection process.

There is a laser safety file in place that contains all of the relevant information relating to the IPL and laser equipment.

Evidenced by:

Discussion with staff
Review of policies and procedures
Review of information provided to clients
Review of local rules
Review of medical treatment protocols
Review of IPL and laser registers
Review of client 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 Other areas examined

Private Doctor Service

As the medical practitioner working with the establishment is now wholly private the services provided by this practitioner also fall under the regulation of RQIA.

The inspector discussed with the registered provider/manager the provision of the private doctor service including botox and dermafillers injections and a requirement was made to ensure that medical treatment protocols, policies and procedures are developed for all other services provided by the medical practitioner.

A further requirement was made to include the services provided by the private medical practitioner within the Statement of Purpose and Client Guide.

Review of records regarding the medical practitioner confirmed:

- There was evidence of current registration with the General Medical Council (GMC)
- The medical practitioner is covered by the appropriate professional indemnity insurance
- The medical practitioner had provided evidence of experience in laser, IPL and aesthetic procedures
- There was evidence of ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and GMC
- There was evidence of ongoing annual appraisal by a trained medical appraiser
- A responsible officer had been appointed

There was written information available regarding the services provided by the private doctor which were written in plain English and were in line with General Medical Council (GMC) Good Medical Practice.

8.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Mrs Therese McKeown 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



Quality Improvement Plan

Announced Inspection

Laserase Clinic

31 October 2014

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 Therese McKeown during 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.

| | ations (Northern Irelan | | MUMPER OF | DETAIL O OF ACTION TAICEN | TIMECOALE |
|-----|-------------------------|---|------------------------------|---------------------------|---------------------------------------|
| NO. | REGULATION REFERENCE | REQUIREMENTS | NUMBER OF TIMES STATED | BY REGISTERED PERSON(S) | TIMESCALE |
| 1 | 15 (2) (a) | 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. Ref: Standard 48 | Two | Sorted | Immediately |
| 2 | 18 (2) (a) | The registered provider/manager must ensure that all authorised users complete the mandatory training as outlined in the main body of the report. Ref: Standard 48 | One | Completed | Within three months and ongoing |
| 3 | 39 (2) | 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 | One | Conflited | Within one month |

STATUTORY REQUIREMENTS

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Regulations (Northern Ireland) 2011.

| NO. | REGULATION REFERENCE | REQUIREMENTS | NUMBER OF TIMES STATED | DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S) | TIMESCALE |
|-----|-------------------------|--|------------------------------|--|------------------------|
| 4 | 9A (1) (b) | The registered provider/manager must ensure that policies, procedures and medical treatment protocols are developed for all other services provided by the medical practitioner. Ref: 7.0 | One | Completed | Within three months |
| 5 | 9 (a) | The registered provider/manager must ensure that Statement of Purpose and Client Guide are updated to include the provision of the private doctor service. Ref: 7.0 | One | Completed | Within three months |

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.

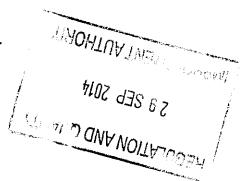
| WITH G | Cirvery. | | | | |
|--------|----------------------------------|--|---------------------------|---|---------------------------------------|
| NO. | MINIMUM STANDARD REFERENCE | RECOMMENDATIONS | NUMBER OF TIMES STATED | DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S) | TIMESCALE |
| 1 | 5.2 | 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. Ref: Standard 5 | One | Completed | Immediately and ongoing |
| 2 | 48.13 | 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, receive laser safety awareness training annually and a record retained. | One | Completed | Within three months and ongoing |
| | | Ref: Standard 48 | | | |

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 | There 4° Keon |
|--|---------------|
| Name of Responsible Person / Identified Responsible Person Approving QIP | Thee McKeon |

| QIP Position Based on Comments from Registered Persons | Yes | Inspector | Date |
|--|-----|-----------|--------|
| Response assessed by inspector as acceptable | | Brome | 9/2/15 |
| Further information requested from provider | | | |





Pre-Inspection Self-Assessment Laser/IPL Service

Name of Establishment:

Laserase Clinic

Establishment ID No:

10633

Date of Inspection:

7-October 2014

T.B.A.

Inspector's Name:

Jo Browne

Inspection No:

18575

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

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The aim of inspection is to examine the policies, procedures, practices and monitoring arrangements for the provision of laser/IPL services, and to determine the provider's compliance with the following:

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- 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? | | <u> </u> |
| Have any changes been made to the management structure of the establishment since the previous inspection? | | V |
| Yes, please comment | | |
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Policies and Procedures

| 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 | |
|--|---|
| Are the policies and procedures for all operational areas in line with | T |
| 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 client? | | |
| Are arrangements in place to securely store client care records? | | |
| No, please comment | | To provide the second of |

Patient Partnerships

| | YES | NO |
|--|-----|----|
| Does the establishment have systems in place to obtain the views of clients regarding the quality of treatment, care and information provided? | | |
| Does the establishment make available a summary report of client feedback to clients and other interested parties? | | |
| No, please comment | | |

Medical Emergencies

| | YES | NO |
|---|-----|----|
| Are arrangements in place to deal with medical emergencies? | | |
| No, please comment | | |
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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 | | |
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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 | | |
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Infection Prevention and Control

| Does the establishment have an infection prevention and control policy | |
|---|--|
| and procedure in place? | |
| Are appropriate arrangements in place to decontaminate equipment between clients? | |
| No, please comment | |

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 training records available which confirm that the following mandatory undertaken: | training h | as been |
| 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 | V | |
| 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 | | |

<u>Appraisal</u>

| | 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 | | |
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Qualifications of 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? | V | |
| 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? | 1 | |
| No, please comment | | |
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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? | <u></u> | |
| 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? | V | |
| Does the establishment have arrangements in place for maintenance and servicing of equipment in line with manufacturer's guidance? | V | |
| Does the establishment have protective eyewear in place, as outlined in the local rules? | | |
| Is the controlled area clearly defined? | 1 | |
| 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? | 125 |
|---|-----|
| No, please comment | , |
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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 |
|----------------|--------------|-------------|---------|
| THERESE WEREOM | Thire Mc Ken | Director | 22/9/14 |