

Announced Follow-up Care and Variation to Registration Inspection Report 23 November 2018 and 3 December 2018



Abrade Tattoo Removal

**Type of Service: Independent Hospital (IH) –
Cosmetic Laser Service**

Address: 53 Spencer Road, Derry BT47 6AA

Tel No: 028 7131 3023

Inspector: Norma Munn

RQIA's Medical Physics Advisor: Dr Ian Gillan

www.rgia.org.uk

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 service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

This is an Independent Hospital (IH) – Cosmetic Laser Service. Types of treatment provided are laser hair removal and laser tattoo removal.

Laser equipment:

Manufacturer: Lumenis
 Model: Light Sheer
 Serial Number: T5086
 Laser Class: 4
 Wavelength: 790 – 830nm

Types of Treatment Provided: Laser hair removal

Laser equipment:

Manufacturer: ADL
 Model: Sapphire II
 Serial Number: S2261112279
 Laser Class: 4
 Wavelength: 532nm and 1064nm

Types of Treatment Provided: Laser tattoo removal

Laser protection advisor (LPA):

Mr Irfan Azam (Lasernet)

Laser protection supervisor (LPS):

Mr Anthony O'Neill

Medical support services:

Dr Paul Myers

Authorised operators:

Mr Anthony O'Neill
 Mr David Marshall
 Ms Melissa Wall
 Ms Nicole Doherty

3.0 Service details

Organisation/Registered Providers: Mr Anthony O'Neill Mr David Marshall	Registered Manager: Mr David Marshall
Persons in charge at the time of inspection: Mr Anthony O'Neill Mr David Marshall	Date manager registered: 21 December 2017
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers	

4.0 Inspection summary

An announced follow up care and variation to registration inspection took place on 23 November 2018 from 10.00 to 14.15. The inspector was accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor. An issue was identified in respect of laser safety and a further visit to the registered establishment was conducted by Dr Gillan on 3 December 2018 to conclude the inspection. Dr Gillan's findings and report are appended to this report.

A previous announced care inspection of Abrade Tattoo Removal had been undertaken on 20 September 2018. During the inspection eight areas for improvement were identified against the regulations and six areas for improvement were identified against the standards. It was agreed that a follow-up care inspection would be undertaken. Subsequently, RQIA undertook an announced follow up care inspection of Abrade Tattoo Removal on 23 November 2018.

An application for variation to the registration of this establishment was submitted to RQIA by Mr Anthony O'Neill and Mr David Marshall, registered persons, to provide laser tattoo removal and laser hair removal using the same laser equipment in a different location to the address registered.

The focus of this inspection was to ascertain the progress made to address the areas of improvement identified as a result of the previous care inspection undertaken on 20 September 2018 and review the readiness of Abrade Tattoo Removal for the provision of laser tattoo removal and hair removal associated with the application for variation of registration.

Mr Raymond Sayers, estates inspector, completed a desktop review of the application and has been in contact with the practice and requested specific documents in relation to the premises to be submitted for review.

The inspection evidenced that significant progress had been made towards achieving compliance with the areas for improvement identified at previous the inspection on 20 September 2018. No areas for improvement have been made as a result of this inspection.

In relation to the application to vary the registration of Abrade Tattoo Removal, RQIA propose to proceed to approval of the application placing the following condition on the registration:

Laser tattoo removal and hair removal will be provided in Unit 8, Dungannon Enterprise Centre, Coalisland Road, BT71 6JT on a Wednesday only. The following equipment only to be used on the Dungannon Site:

Laser tattoo removal: Q-switch Nd Yag, ADL Sapphire II laser machine, serial number S2261112279

Hair removal: Lumenis Lightsheer serial number T5086

In order to progress with the application, RQIA has requested that Mr O'Neill and Mr Marshall agree to the condition above in writing. Once this has been received by RQIA then the variation can be approved from a care perspective.

This inspection was underpinned by The Health and Personal Social Services (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 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, and enhance practice and clients' experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mr O'Neill, registered person, as part of the inspection process and can be found in the main body of the report.

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

4.2 Action/enforcement taken following the most recent care inspection dated 20 September 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 20 September 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- the submitted variation of registration application
- the statement of purpose
- the client guide
- laser safety documentation
- policies and procedures
- the returned quality improvement plan (QIP) for the previous care inspection

During the inspection the inspector and Dr Gillan met with Mr O'Neill and Mr Marshall, registered persons. A tour of the registered premises in Derry and the premises in Dungannon associated with the application for variation to registration was also undertaken.

The following records were also examined during the inspection:

- policies and procedures
- revised statement of purpose
- revised client guide
- training records
- laser safety file
- laser equipment documentation
- cleaning schedules

Areas for improvement identified at the last care inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to Mr O'Neill at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 20 September 2018

The most recent inspection of the establishment was an announced care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 20 September 2018

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		Validation of compliance
Area for improvement 1 Ref: Regulation 39 (2) Stated: First time	The registered persons shall ensure that the laser safety file contains accurate and relevant information in relation to: <ul style="list-style-type: none"> • the details of the current certified laser protect advisor (LPA) • a set of local rules for the laser equipment in place 	Met
	Action taken as confirmed during the inspection: The laser safety file reviewed contained accurate and relevant information in relation to the details of the LPA and the local rules for the laser equipment in place.	

<p>Area for improvement 2</p> <p>Ref: Regulation 39 (1)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that:</p> <ul style="list-style-type: none"> • copies of the medical treatment protocols referred to in the medical support certificate are retained • the medical treatment protocols are subject to continuous review by a named medical practitioner 	<p style="text-align: center;">Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>A review of documentation confirmed that copies of the medical treatment protocols referred to in the medical support certificate had been retained and reviewed by Dr Paul Myers.</p>		
<p>Area for improvement 3</p> <p>Ref: Regulation 39 (2)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that the most recent site audit report completed by the laser protection advisor (LPA) accurately reflects the details of the laser equipment on site. Any recommendations made should be addressed and signed and dated on completion.</p>	<p style="text-align: center;">Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>The most recent site audit report completed by the LPA was reviewed and reflected the details of the laser equipment on site. Discussion with Mr O'Neill and a review of the report confirmed that the recommendations made had been addressed.</p>		
<p>Area for improvement 4</p> <p>Ref: Regulation 39 (2)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that the protective eyewear provided is as outlined in the local rules.</p>	<p style="text-align: center;">Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>The protective eyewear provided was not as outlined in the local rules. A further visit was made to the establishment by Dr Gillan on 3 December 2018 and during this visit Dr Gillan confirmed that the protective eyewear provided was as outlined in the local rules.</p>		

<p>Area for improvement 5</p> <p>Ref: Regulation 39 (2)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that the laser registers are updated to include the information listed below every time the laser machines are used:</p> <ul style="list-style-type: none"> • the name of the person treated • the date • the name of the operator • the actual treatment given and area of the body • the precise exposure • any accident or adverse incident 	Met
<p>Action taken as confirmed during the inspection:</p> <p>A review of the laser registers and discussion with Mr O'Neill and Mr Marshall confirmed that every time the laser has been used the information listed above has been recorded.</p>		
<p>Area for improvement 6</p> <p>Ref: Regulation 15 (2) (b)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that all laser equipment is serviced in line with manufacturer's instructions.</p>	Met
<p>Action taken as confirmed during the inspection:</p> <p>The laser equipment had been serviced and copies of the servicing certificates had been retained.</p>		
<p>Area for improvement 7</p> <p>Ref: Regulation 25 (4) (d) (e) (f)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that the fire risk assessment is reviewed annually, routine fire safety checks are carried out and recorded and fire drills are undertaken annually.</p>	Met
<p>Action taken as confirmed during the inspection:</p> <p>The fire risk assessment had been reviewed, routine fire safety checks had been carried out and recorded and RQIA received confirmation following the inspection that a fire drill had been undertaken.</p>		

<p>Area for improvement 8</p> <p>Ref: Regulation 21 (1) (3)</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that an accurate and up to date treatment record is maintained for every client that includes:</p> <ul style="list-style-type: none"> • client details • medical history • signed consent form • skin assessment • patch test (where appropriate) • record of treatment delivered including the number of shots and fluence settings (where appropriate) <p>Action taken as confirmed during the inspection: A review of three client treatment records evidenced that an accurate and up to date treatment record had been maintained.</p>	<p>Met</p>
<p>Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)</p>		<p>Validation of compliance</p>
<p>Area for improvement 1</p> <p>Ref: Standard 10.6</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that all authorised operators have an appraisal carried out on an annual basis.</p> <p>Action taken as confirmed during the inspection: Mr O'Neill confirmed that appraisals had been scheduled to take place on 3 December 2018.</p>	<p>Met</p>
<p>Area for improvement 2</p> <p>Ref: Standard 3.9</p> <p>Stated: First time</p>	<p>The registered persons shall ensure that all authorised operators complete safeguarding adults training commensurate with their role in keeping with RQIA training guidance and as outlined in the Minimum Care Standards for Independent Healthcare Establishments (July 2014).</p> <p>Action taken as confirmed during the inspection: Discussion with Mr O'Neill and a review of training records confirmed that all authorised operators had completed safeguarding adults training in keeping with RQIA training guidance.</p>	<p>Met</p>

Area for improvement 3 Ref: Standard 2.3 Stated: First time	The registered persons shall ensure that consent is obtained and recorded before providing any treatment.	Met
	Action taken as confirmed during the inspection: Discussion with Mr O'Neill and a review of client treatment records confirmed that consent had been obtained and recorded before providing any treatment.	
Area for improvement 4 Ref: Standard 8.5 Stated: First time	The registered persons shall ensure that the establishment is registered with the Information Commissioners Office (ICO).	Met
	Action taken as confirmed during the inspection: A review of documentation confirmed that the establishment had registered with the ICO and the registration certificate had an expiry date of 4 October 2019.	
Area for improvement 5 Ref: Standard 12.7 Stated: First time	The registered persons shall ensure that staff meetings take place on a regular basis, at least quarterly and the minutes of the meetings are retained.	Met
	Action taken as confirmed during the inspection: Discussion with Mr O'Neill and a review of staff meeting minutes confirmed that recent staff meetings had taken place. Mr O'Neill has confirmed that staff meetings will take place on a regular basis.	
Area for improvement 6 Ref: Standard 5.1 Stated: First time	The registered persons shall ensure that a client satisfaction survey is carried out annually that includes the quality of treatment and other services provided.	Met
	Any feedback provided by clients should be collated into an anonymised format, summarised and used to inform and improve services provided. The summary report should be made available to clients and other interested parties.	

	<p>Action taken as confirmed during the inspection: Discussion with Mr O'Neill and a review of documentation confirmed that client satisfaction surveys have been carried out since the previous inspection. Mr O'Neill confirmed that feedback provided by clients will be collated into an anonymised format, summarised and used to inform and improve services provided. The summary report will be made available to clients and other interested parties.</p>	
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6.3 Variation to registration inspection findings

As discussed, an application for variation to the registration was submitted to RQIA to provide laser tattoo removal and laser hair removal using the same laser equipment in a different location to the address registered. This inspection reviewed the readiness of Abrade Tattoo Removal for the provision of laser tattoo removal and hair removal associated with the application of variation.

Statement of purpose

A statement of purpose was reviewed prior to the inspection and was prepared in a recognised format which covered the key areas and themes outlined in Regulation 7, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. However, the statement of purpose did not include accurate details of the proposed variation to registration as outlined in the application. A revised statement of purpose was reviewed during the inspection and included the types of treatment, the address of the proposed premises and the specific days of the week the treatment will be offered as outlined in the submitted application.

Client guide

A client guide was reviewed prior to the inspection and was prepared in a recognised format which covered the key areas and themes specified in Regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005. However, the client guide did not include accurate details of the proposed variation to registration as outlined in the application. A revised client guide was reviewed during the inspection and included the treatment that will be offered as outlined in the submitted application.

Environment

A tour of the premises located at Unit 8, Dungannon Enterprise Centre, Coalisland Road, Dungannon BT71 6JT associated with the application for variation to registration was undertaken.

It was confirmed that one treatment room on the first floor of the premises in Dungannon will be used either for laser tattoo removal or laser hair removal by Abrade Tattoo Removal on a Wednesday only using the same laser equipment as used in the premises in Derry. Although a wide range of services and treatments is currently offered in the premises in Dungannon, this

inspection focused solely on those that fall within regulated activity and the category of care for which the establishment is registered with RQIA.

The treatment room was maintained to a good standard of maintenance and décor. Detailed cleaning schedules were in place.

A fire risk assessment had been undertaken and Mr O'Neill confirmed fire training and fire drills had been completed. Mr O'Neill was aware of the action to take in the event of a fire.

As discussed, Mr Raymond Sayers, estates inspector completed a desktop review of the application and has been in contact with the practice and requested specific documents in relation to the premises to be submitted for review.

Infection prevention and control and decontamination procedures

The treatment room was observed to be clean, tidy and clutter free. Mr O'Neill confirmed that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. Mr O'Neill confirmed that all authorised operators have up to date training in infection prevention and control.

Procedures for the use of lasers

Mr O'Neill confirmed that laser procedures will be carried out by trained authorised operators in accordance with medical treatment protocols produced by Dr Paul Myers on 30 May 2018.

Systems are in place to review the medical treatment protocols every year.

The medical treatment protocols set out:

- contraindications
- technique
- pre-treatment tests
- pre-treatment care
- post-treatment care
- recognition of treatment-related problems
- procedure if anything goes wrong with treatment
- permitted variation on machine variables
- procedure in the event of equipment failure

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

A risk assessment of the premises in Dungannon was undertaken by the LPA during June 2018 and all issues identified have been addressed by the LPS. The establishment has local rules in place which have been developed by their LPA during June 2018.

The local rules cover:

- the potential hazards associated with lasers and intense light sources
- controlled and safe access
- authorised operators' responsibilities

- methods of safe working
- safety checks
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

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

Laser operators are authorised to use the equipment and a register of authorised operators is maintained. Authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

Laser registers have been established for each laser machine to record the following information each time the laser is used as required by legislation:

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

Records will be retained in manual format and appropriate systems and processes are in place for the management of records and maintaining client confidentiality.

Safe operation of lasers

The treatment room in which the lasers will be used was found to be controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

When the equipment is in use, the safety of all persons in the controlled area is the responsibility of Mr O'Neill.

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

Mr O'Neill confirmed that the protective eyewear used in the premises in Dungannon would be the same protective eyewear as used in the premises in Derry. However, the protective eyewear observed did not provide the protection level detailed in the local rules. In addition, the specific local rules for the premises in Derry and the premises in Dungannon detailed different protection level requirements for the eyewear. This was discussed and it was agreed that a further visit to Abrade Tattoo Removal would be undertaken to review this information. On 3 December 2018, Dr Gillan visited the premises in Derry and confirmed that suitable protective eyewear had been provided and the discrepancy between the local rules corrected.

Mr O'Neill confirmed that the door to the treatment room will be locked when the laser equipment is in use and can be opened from the outside in the event of an emergency.

Mr O'Neill confirmed that there are formal written arrangements in place for the safe custody of the laser keys.

There is a separate laser safety file in place in relation to the premises in Dungannon.

Equipment has been serviced and maintained in line with the manufacturers' guidance.

A carbon dioxide (CO₂) extinguisher suitable for electrical fires was available in the corridor close to the treatment room.

Recruitment of staff

Mr O'Neill confirmed that no authorised operators have been recruited since the previous inspection. Mr O'Neill also confirmed that the authorised operators who carry out treatments in the premises in Dungannon will be the same authorised operators who carry out treatment in the premises in Derry. During discussion it was confirmed that, should authorised operators be recruited in the future, robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

Staff training and development and training for staff using lasers

A record of training was available for all authorised operators in keeping with RQIA training guidance for cosmetic laser services.

A review of the training records confirmed that core of knowledge training, the safe use and application of the laser training, infection prevention and control, basic life support, fire safety and safeguarding adults at risk of harm training had been completed.

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

Management of emergencies

As discussed, authorised operators have up to date training in basic life support. Discussion with Mr O'Neill confirmed they he was aware what action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.4 Conclusion

The care inspector was satisfied with the new arrangements associated with the variation application. As discussed RQIA propose to proceed to approval of the application placing the following condition on the registration:

Laser tattoo removal and hair removal will be provided in Unit 8, Dungannon Enterprise Centre, Coalisland Road, BT71 6JT on a Wednesday only. The following equipment only to be used on the Dungannon Site:

Laser tattoo removal: Q-switch Nd Yag, ADL Sapphire II laser machine, serial number S2261112279

Hair removal: Lumenis Lightsheer serial number T5086

In order to progress with the application, RQIA has requested that Mr O'Neill and Mr Marshall, registered persons agree to the condition above in writing. Once this has been received by RQIA the variation can be approved from a care perspective.

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a QIP is not required or included as part of this inspection report.

4th December 2018

Mrs N Munn
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Mrs Munn

Laser Protection Report

Abrade Tattoo Removal, 53 Spencer Road, Londonderry BT47 6AA

Date of visit 23rd November & 3rd December 2018

*Abrade Tattoo Removal, Unit 8 Dungannon Enterprise Centre, Coalsland Road,
Dungannon BT71 6JT*

Date of visit 23rd November 2018

Summary

The laser protection arrangements are now satisfactory

Introduction

Further to the inspection visits to the above premises this report summarises the main laser protection aspects where improvement may be required. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Deficiencies / Comments

Lumenis Lightsheer (protective Eyewear)

23rd November 2018 inspection - The protective eyewear for use by the operator did not provide the protection level detailed in the local rules. In addition the specific local Rules for each of the clinics detailed different protection level requirements for the eyewear.

3rd December 2018 inspection – Suitable eyewear was available in the clinic and the discrepancy between the local rules corrected.

Door Lock at Dungannon Enterprise Centre

There is a requirement to lock the treatment room door to maintain security of the equipment and records, however during treatment sessions it is important that someone in the building have access to a key to gain entry to the room in an emergency. The clinic agreed to ensure that arrangements were in place.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Laser Systems

Abrade Tattoo Removal, 53 Spencer Road, Londonderry BT47 6AA

Hair Removal laser

Manufacturer	Lumenis
Model	Lightsheer
Serial Number:	T5086
Output wavelength:	790 – 830nm
Laser Class:	4

Tattoo Removal laser

Manufacturer	ADL
Model	Saphire
Serial Number:	52261112279
Output wavelength:	532nm & 1064nm
Laser Class:	4

Laser Protection Adviser

Lasernet

Date of last visit June 2018



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