

Inspection Report

20 May 2021



The Laser Clinic Northern Ireland

Type of service: Independent Hospital – Cosmetic Laser Service
Address: Unit 3, 29 Ballymoney Street, Ballymena, BT43 6AN
Telephone number: 07464 892 857

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

Information on legislation and standards underpinning inspections can be found on our website [https://www.rqia.org.uk/The Independent Health Care Regulations \(Northern Ireland\) 2005 and Minimum Care Standards for Independent Healthcare Establishments \(July 2014\)](https://www.rqia.org.uk/The_Independent_Health_Care_Regulations_(Northern_Ireland)_2005_and_Minimum_Care_Standards_for_Independent_Healthcare_Establishments_(July_2014))

1.0 Service information

<p>Organisation/Registered Provider: Judith Laverty t/a The Laser Clinic Northern Ireland</p>	<p>Registered Manager: Mrs Kirsty McNaughton</p> <p>Date registered: 10 June 2021</p>
<p>Person in charge at the time of inspection: Mrs Kirsty McNaughton</p>	
<p>Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers</p>	
<p>Brief description of how the service operates: The Laser Clinic Northern Ireland (NI) provides laser treatments to persons over the age of 18 years. This inspection focused on treatments using a Class 4 laser that fall within regulated activity and the categories of care for which the establishment is registered with RQIA.</p> <p>Miss Judith Laverty is also the registered manager and registered manager of The Laser Clinic NI located in Belfast.</p> <p>Equipment available in the service:</p> <p>A new laser machine has been provided since the last inspection undertaken on 27 September 2019.</p> <p>Current laser equipment: Manufacturer: Asclepion Laser Technologies Model: MeDioStar Serial Number: 159X00402</p> <p>Treatment Modules: STD Diode 800nm Class 4 laser HP Diode 800nm Class 4 laser VAS Diode 950nm Class 4 laser</p> <p>Laser protection advisor (LPA): Ms Anna Bass, Lasermet</p> <p>Laser protection supervisor (LPS): Miss Judith Laverty</p>	

Medical support services: Dr Paul Myers

Authorised operators: Ms Josephine Robb and Ms Donna Murphy

Types of laser treatments provided:

- hair reduction
- acne

2.0 Inspection summary

This was an announced inspection undertaken by a care inspector and the Laser Protection Advisor (LPA) for RQIA on 20 May 2021 from 10:00 am to 12.30 pm.

Due to the COVID-19 pandemic the Northern Ireland (NI) Executive issued The Health Protection (Coronavirus, Restrictions) (No. 2) (Amendment) Regulations (Northern Ireland) 2020. These regulations specified close contact services that should close for identified periods of time; as a result of these periods of closure The Laser Clinic NI was not inspected by RQIA during the 2020-21 inspection year.

In March 2021 Miss Judith Lavery submitted a variation to registration application in respect of The Laser Clinic NI. This application was to relocate the establishment premises to Unit 3, 29 Ballymoney Street, Ballymena, BT43 6AN. An application was also submitted for the registration of Mrs Kirsty McNaughton as the registered manager.

The purpose of the inspection was to assess progress with areas for improvement identified during the last care inspection, assess compliance with the legislation and minimum standards and review the readiness of the establishment associated with the variation to registration application.

The LPA for RQIA reviewed the safety measures in place to manage and maintain the current laser. The findings and laser safety report are appended to this report.

An RQIA estates support officer, reviewed the variation to registration application in relation to matters relating to the premises.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; laser safety; management of medical emergencies; infection prevention and control (IPC); adherence to best practice guidance in relation to COVID-19; the management of clinical records; and effective communication between clients and staff. Additional areas of good practice were identified included maintaining client confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

No immediate concerns were identified regarding the delivery of front line client care.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the establishment is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the Quality Improvement Plan (QIP).

4.0 What people told us about the service

The Laser Clinic NI has not been operational since 2019 due to the impact of the COVID-19 pandemic and other extenuating circumstances and in the interim has moved to new premises. Clients have not yet had access to the new premises therefore clients were unable to tell us about this service. Mrs McNaughton outlined how client feedback will be sought and used to make improvements as applicable when the service becomes operational.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

Areas for improvement from the last inspection on 27 September 2019		
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)		Validation of compliance
Area for Improvement 1 Ref: Regulation 48 Stated: First time	The registered person should ensure that the issues identified in the LPA's risk assessment action plan, dated 23 September 2019, are addressed by the LPS and the action plan signed and dated in this regard.	No longer relevant
	Action taken as confirmed during the inspection: As discussed this service has not been operational since 2019. The previous LPA report, dated 23 September 2019 has been superseded by the new updated and current LPA risk assessment, and is discussed in section 5.2.8 of this report.	

Area for Improvement 2 Ref: Standard 48.20 Stated: First time	The registered person should ensure that a manufacturer's service is undertaken for the laser machine prior to recommencement of laser treatments.	No longer relevant
	Action taken as confirmed during the inspection: This area for improvement refers to the previous laser machine and is no longer relevant. The servicing arrangements in relation to the new laser are outlined in section 5.2.8 of this report.	
Area for Improvement 3 Ref: Standard 22.3 Stated: First time	The registered person should ensure that the floor covering in the treatment room is secured at the edging to facilitate effective cleaning and also to reduce the risk of a tripping accident occurring.	No longer relevant
	Action taken as confirmed during the inspection: This area for improvement refers to the previous premises and is therefore not relevant to this inspection.	

5.2 Inspection outcome

5.2.1 How does this service ensure that staffing levels are safe to meet the needs of clients?

Discussion with staff demonstrated that there are sufficient staff in the various roles to fulfil the needs of the establishment and clients.

Staff confirmed that laser treatments are only carried out by authorised users. A register of authorised users for the laser is maintained and kept up to date.

A review of completed induction programmes evidenced that induction training is provided to new staff on commencement of employment.

A review of training records evidenced that authorised users have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety awareness and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

Arrangements are in place to provide any other staff employed at the establishment, who are not directly involved in the use of the laser equipment, with laser safety awareness training.

5.2.2 How does the service ensure that recruitment and selection procedures are safe?

A robust recruitment and selection policy and procedure, that adhered to legislation and best practice guidance for the recruitment of authorised operators, was in place. These arrangements ensure that all required recruitment documentation has been sought and retained for inspection. A review of two personnel files of authorised operators confirmed that staff have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

5.2.3 How does the service ensure that is equipped to manage a safeguarding issue should it arise?

Staff informed us that laser treatments are not provided to persons under the age of 18 years.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

Discussion with staff confirmed that they were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Review of records demonstrated that Miss Laverty, as the safeguarding lead, has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards. Training records reviewed also evidenced that all the authorised operators have completed the appropriate safeguarding training in respect of their role and responsibilities.

It was confirmed that copies of the regional policy entitled Co-operating to Safeguard Children and Young People in Northern Ireland (August 2017) and the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) were both available for reference.

The service had appropriate arrangements in place to manage a safeguarding issue should it arise.

5.2.4 How does the service ensure that medical emergency procedures are safe?

All authorised operators had up to date training in basic life support, discussion with staff demonstrated they were aware of what action to take in the event of a medical emergency. There was a resuscitation policy in place and a review of this evidenced that it was comprehensive, reflected legislation and best practice guidance.

The service had appropriate arrangements in place to manage a medical emergency.

5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?

The IPC arrangements were reviewed throughout the establishment to evidence that the risk of infection transmission to clients, visitors and staff was minimised.

There was an overarching IPC policy and associated procedures in place. A review of these documents demonstrated that they were comprehensive and reflected legislation and best practice guidance in all areas.

The laser treatment room was clean and clutter free. Discussion with staff evidenced 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. As discussed previously, authorised operators have up to date training in infection prevention and control.

The service had appropriate arrangements in place in relation to IPC and decontamination.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular, businesses need to consider the risks to their clients and staff.

The management of operations in response to the COVID-19 pandemic were discussed with staff who outlined the measures that will be taken by The Laser Clinic NI to ensure current best practice measures are in place. Appropriate arrangements are in place in relation to maintaining social distancing; implementation of enhanced IPC procedures; and the client pathway to include COVID-19 screening prior to attending appointments.

The proposed management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

5.2.7 How does the service ensure the environment is safe?

The service has one treatment room and access to storage rooms. The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Observations made evidenced that a carbon dioxide (CO₂) fire extinguisher is available which has been serviced within the last year.

As discussed, an RQIA estates support officer undertook a desktop review of the variation to registration application to move premises and corresponded directly with Miss Laverty about matters relating to the premises. This variation has been approved from an estates perspective.

It was determined that appropriate arrangements were in place to maintain the environment.

5.2.8 How does the service ensure that laser procedures are safe?

A laser safety file was in place which contained the relevant information in relation to laser equipment. 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 1 March 2022.

Up to date local rules were in place which have been developed by the LPA. It was identified that the treatment wavelengths outlined in the local rules were not the same as stated in the medical treatment protocols prepared by Dr Myers, author of the medical treatment protocols. Mrs McNaughton was advised to discuss this matter with Dr Myers and the LPA.

Following the inspection updated local rules and medical treatment protocols were provided which reflected that the treatment wavelengths were the same in all documents and match the actual output wavelengths of the laser equipment.

In addition to the treatment protocols a laminated guide for setting the laser parameters was provided in the treatment room. The clinic was advised to ensure that Dr Myers approves the use of this additional guide or alternatively they remove it from the treatment room. On 15 June 2021 RQIA received email correspondence which confirmed that the laminated guide had been removed from the treatment room.

The establishment's LPA completed a risk assessment of the premises on 15 February 2021 and all recommendations made by the LPA have been addressed.

Staff told us that laser procedures are carried out following medical treatment protocols. As previously discussed the medical treatment protocols had been produced by Dr Myers, a registered medical practitioner. Systems are in place to review the medical treatment protocols when due. The medical treatment protocols contained the relevant information about the treatments being provided.

Miss Laverty, as the laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Authorised operators had signed to state that they had read and understood the local rules and medical treatment protocols.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The door to the treatment room is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser is operated using a key which was noted to be insitu during the inspection. Staff confirmed that arrangements are in place for the safe custody of the key when not in use and advised the key was only in place should the laser needed to be turned on for demonstration purposes. Staff confirmed they were aware of the arrangements to ensure the laser key is not left unattended in the machine at any time.

Protective eyewear for the client and operator was available in the clinic. The protective eyewear for the operator had cracked lenses and it was evidenced that an order had been placed for two additional pairs. It was noted that a pair of total blocking shields was also available for the client as outlined in the local rules. On 9 June 2021 photographic evidence was provided to RQIA by email which confirmed that two new sets of protective eyewear goggles were in place for the client and the operator as outlined in the local rules.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. The lock on the treatment room door is fitted with a thumb turn on the inside and a keyway on the outside. To ensure that access can be gained to the room to assist persons in the room during any incident a key should be placed in a break glass close to the door. On 28 May 2021 RQIA received email correspondence from Mrs McNaughton confirming that a break glass key box had been installed on the outer wall of the controlled area and close to the door.

Staff were aware that the laser safety warning signs should only be displayed when the laser equipment is in use and removed when not in use.

A laser register was in place and staff confirmed that the relevant sections of the register will be completed every time the equipment is operated to include the following information:

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

A service or installation report was not available at the time of the inspection however the clinic agreed to contact the laser engineer to ensure that a report was available. On 9 June 2021 RQIA received a copy of the installation report by email. It was also confirmed that arrangements were in place to service and maintain the laser equipment in line with the manufacturer's guidance. Mrs McNaughton is aware that the laser service records should be retained in the laser safety file and available for future inspections.

It was noted there was taping on the flexible tube at the treatment head of the laser and the clinic was advised to bring this to the attention of the laser engineer and indicate whether this requires further attention. On 3 June 2021 RQIA received confirmation that the laser engineer had documented that the flexible tubing was taped to protect the rubber sheath from wear and chaffing. As taping of an appliance is not conducive with good infection control practice, the taping was discussed with Mrs McNaughton who told us that the laser head and tubing are completely covered with cling film during each laser treatment. Mrs McNaughton stated that the cling film is removed following each treatment and the laser head and tubing cleaned. It was confirmed that this procedure is documented and will be followed by all authorised operators.

It was determined that appropriate arrangements were in place to operate the laser equipment.

5.2.9 How does the service ensure that clients have a planned programme of care and have sufficient information to consent to treatment?

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 service has a list of fees available for each laser 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.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner (GP), with their consent, for further information if necessary.

Client care records were discussed with staff who confirmed that an accurate and up to date treatment record will be maintained for every client which will include:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

Observations made evidenced that client records are to be securely stored in a locked filing cabinet located in an office/storage area which will also be kept locked. A policy and procedure was available which included the creation, storage, recording, retention and disposal of records and data protection.

There is written information for clients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The service has a policy for advertising and marketing which is in line with legislation.

5.2.10 How does the service ensure that clients are treated with dignity respect and involved in the decision making process?

Discussion with staff regarding the consultation and treatment process confirmed that clients are treated with dignity and respect. The consultation and treatment are provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely in a lockable storage case.

Mrs McNaughton told us that clients are encouraged to complete a satisfaction survey when their treatment is complete and that the results of these are collated to provide a summary report which is made available to clients and other interested parties. Mrs McNaughton confirmed that an action plan would be developed to inform and improve services provided, if appropriate.

5.2.11 How does the registered person assure themselves of the quality of the services provided?

Where the entity operating the service is a corporate body or partnership or an individual owner who is not in day to day management of the service, Regulation 26 unannounced quality monitoring visits must be undertaken and documented every six months. It was established that Miss Laverty is no longer in day to day charge of the service, therefore Regulation 26 unannounced quality monitoring visits will apply in the future. These monitoring visit reports will be reviewed during future inspections of the establishment.

Policies and procedures were available outlining the arrangements associated with the laser treatments. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis or more frequently if required.

A copy of the complaints procedure was available in the establishment. Staff evidenced a good awareness of complaints management.

Mrs McNaughton demonstrated that a system was in place to ensure that notifiable events would be investigated and reported to RQIA or other relevant bodies as appropriate.

Mrs McNaughton demonstrated a clear understanding of her new role and responsibilities as registered manager in accordance with legislation.

To date information requested by RQIA has been submitted within the specified timeframes. Mrs McNaughton confirmed that the statement of purpose and client's guide are kept under review. These documents had been revised and updated to reflect the change of address and the current laser treatments provided.

A new certificate of registration will be issued to Miss Laverty following the approval of the variation to registration application. Mrs McNaughton was informed that the new RQIA certificate of registration must be displayed in a prominent place.

Observation of insurance documentation confirmed that current insurance policies were in place.

5.2.12 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients was discussed with staff.

6.0 Conclusion

Based on the inspection findings and discussions held we are satisfied that this service is providing safe and effective care in a caring and compassionate manner; and that the service is well led by the registered person.

The variation to registration application has been approved from a care and estates perspective.

An application was received in respect of Mrs Kirsty McNaughton as registered manager. Following review of the application and discussion with Mrs McNaughton this registered manager application was approved with effect from 10 June 2021.

7.0 Quality Improvement Plan/Areas for Improvement

Findings of the inspection were discussed with Mrs Kirsty McNaughton, Registered Manager, as part of the inspection process. Following the inspection evidence was submitted to RQIA in a timely manner which confirmed the action taken to address the identified areas as discussed in the main body of the report. A quality improvement plan is not required.

21st May 2021

Ms Carmel McKeegan
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Carmel

Laser Protection Report

The Laser Clinic NI (Ballymena), 29 Ballymoney Street, Ballymena BT43 6AN

Introduction

Further to yesterday's visit 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 European Standards and the Control of Artificial Optical Radiation at Work Regulations (Northern Ireland) 2010.

Deficiencies / Comments

(1) Laser Treatment Wavelengths:-

The Clinic's Local Rules indicate that the system is fitted with three treatment modules of STD operating at 800nm, HP operating at 800nm and VAS (Vascular) operating at 950nm

The Clinic's Clinical Treatment Protocols prepared by Dr Myers cover (1) Acne Treatment using a 810nm Diode Laser (2) Hair Removal using a 800nm Diode Laser

Action :- The clinic should discuss this matter with Dr Myers and Lasermet to ensure that the treatment wavelengths are the same in all documents and match the actual output wavelengths of the laser diodes.

(2) Laser Treatment Parameters:- In addition to the Treatment Protocols prepared by Dr Myers a laminated guide for setting the laser parameters was also available in the Treatment Room. The Clinic should ensure that Dr Myers approves of the use of this additional guide or alternatively remove it from the Treatment Room

(3) Laser Key:- When the laser is switched off the key should be removed and kept in safe custody.

(4) Protective Eyewear :- One set of the correct protective eyewear was available in the clinic, as these have cracked lenses an order has been placed for two additional pairs.

One pair of total blocking shields was also available for the client

(5) Servicing:- A service or installation report was not available at the time of the visit however the clinic agreed to contact the Laser Engineer to ensure that a report was available.

The clinic should bring to the attention of the engineer the taping on the flexible tube at the treatment head and ensure that this is repaired or a comment placed in the service report to indicate whether the service engineer recommends further action.

(6) The lock on the treatment room door is fitted with a thumb turn on the inside and a keyway on the outside. To ensure that access can be gained to the room to assist persons in the room during any incident a key should be placed in a break glass close to the door.

The clinic should inform RQIA when the above points have been addressed.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix
Laser Systems

The Laser Clinic NI (Ballymena), 29 Ballymoney Street, Ballymena BT43 6AN

Manufacturer: Asclepion Laser Technologies
Model: MeDioStar
Serial Number: 159X00402

Treatment Modules
STD Diode 800nm Class 4 laser
HP Diode 800nm Class 4 laser
VAS Diode 950nm Class 4 laser

Laser Protection Adviser
Anna Bass, Lasermet



The **Regulation** and
Quality Improvement
Authority

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
 [@RQIANews](https://twitter.com/RQIANews)

Assurance, Challenge and Improvement in Health and Social Care