



The Regulation and
Quality Improvement
Authority

Fitzwilliam Clinic
RQIA ID: 10637
70-72 Lisburn Road
Belfast
BT9 6AF

Inspector: Jo Browne
Inspection ID: IN023575

Tel: 028 9032 3888

**Variation to Registration Inspection
of
Fitzwilliam Clinic**

28 August 2015

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1.0 General Information

Name of establishment:	Fitzwilliam Clinic
Address:	70-72 Lisburn Road Belfast BT9 6AF
Telephone number:	028 9032 3888
Registered Organisation/ Registered Provider:	Fitzwilliam Partnership Mr James Small, Mr John Sinclair & Mr James Kennedy
Registered Manager:	Sheila Jordan
Person-in-charge of the establishment at the time of inspection:	Ms Jenny Flanagan
Registration Categories:	AH (DS) – Acute Hospital Day Surgery PD – Private Doctor PT (L) - Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers
Date and time of inspection:	28 August 2015 10.30 – 11.30
Name of inspector:	Jo Browne
Name of Medical Physics Advisor:	Dr Ian Gillan

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 and this may be announced or unannounced.

3.0 Purpose of Variation Inspection

Fitzwilliam Clinic have applied to RQIA to vary their category of registration to include PT(IL) prescribed techniques or prescribed technology: establishments using intense light sources.

The purpose of the variation inspection is to review the intense pulse light (IPL) equipment introduced by the establishment and to determine compliance with:

- The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005;
- 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
- DHSSPS Minimum Care Standards for Healthcare Establishments, July 2014.

4.0 Methods/ Processes

The methods/ process used in this inspection included the following:

- review of the submitted variation application forms and supported documentation;
- discussion with Ms Jenny Flanagan, authorised user;
- assessment of the environment;
- review of documentation required by legislation and good practice;
- evaluation and feedback.

5.0 Profile of the Establishment

The Fitzwilliam Clinic is situated in a converted residential building located on the Lisburn Road in Belfast. The hospital offers a range of surgical and non-surgical procedures. The clinic has no overnight beds and all surgery is performed as day cases only.

The following procedures are available in the clinic:

Surgery

- Cutaneous surgery
- Oral surgery
- Breast surgery
- Hand surgery
- Aesthetic surgery
- General surgery
- Varicose Vein Treatments using radiofrequency ablation

All surgical procedures are undertaken by consultant surgeons and dental practitioners who have been granted practising privileges by the hospital.

The Registered Manager is Ms Sheila Jordan. Mr Stephen Sinclair is the Medical Director/responsible individual for the hospital. Mr Small and Mr Kennedy are also partners in the business and responsible individuals.

Laser and IPL Services

The hospital has applied to RQIA to vary their category of registration to provide IPL treatments in addition to their existing laser treatments.

Laser Equipment

Manufacturer: Cynosure
Model: Apogee
Serial Number: APMD 1900
Laser Medium: Alexandrite (755nm)
Laser Class: Class 4

Cooler

Manufacturer: Cynosure
Model: Cryo 5
Serial Number: 727985

IPL Equipment

Manufacturer: Lumenis
Model: Quantum SR
Serial Number: 003-02629

Laser Protection Advisor (LPA)

Mr Alex Zarneh

Medical Support Services

Dr Donal McKeown

Laser Protection Supervisor (LPS)

Ms Jenny Flanagan

Authorised Users

Ms Jenny Flanagan

Laser Treatment Provided

Hair removal

IPL Treatment Provided

Skin rejuvenation
Skin pigmentation treatment
Thread vein treatment

6.0 Summary

A variation application was submitted to RQIA by Ms Sheila Jordan in respect of Fitzwilliam Clinic to include the PT (IL) category of care in their registration. This report only refers to the provision of the laser and IPL services.

The application forms and supporting documentation was reviewed as part of the inspection process.

The inspection was carried out by Jo Browne accompanied by Dr Ian Gillan (Medical Physics Advisor for RQIA) on 28 August 2015 between the hours of 10:30 and 11:30.

The inspection was facilitated by Ms Jenny Flanagan, the authorised user of the laser and IPL equipment. Ms Flanagan 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.

A Statement of Purpose and Patient Guide were in place which reflected legislative and best practice guidance; however a recommendation was made to include the IPL services to be offered within the establishment.

Systems were in place to obtain the views of service users.

The establishment had a complaints policy and procedure in place which was found to be in line with the DHSSPS guidance on the management of complaints within regulated establishments and agencies. Systems were in place to effectively document and manage complaints.

A review of training records confirmed that the authorised user had completed the required mandatory training. Staff not involved in the use of the IPL equipment and laser had received laser safety awareness training.

There was a policy and procedure in place for infection prevention and control. The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor. Ms Flanagan had received training in infection prevention and control. Cleaning schedules were in place and arrangements for the decontamination of equipment between clients.

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

The proposed client care records for IPL treatments were examined and found to contain a health questionnaire, consent form and a record of the treatment.

A requirement was made to develop medical treatment protocols for the IPL equipment. There were agreed medical treatment protocols in place for the use of the laser.

The establishment has local rules developed by their LPA and written in June 2015.

A risk assessment of the premises was undertaken by the LPA and no issues were identified.

There was list of authorised users in place.

The environment in which the IPL equipment and laser was used was found to be safe and controlled. Protective eyewear was available for the client and operator. A recommendation was made for the LPA to amend the local rules to reflect the disposable protective eyewear available within the establishment. A further recommendation was made in relation to a record of the LPA's visit being retained by the establishment.

Laser safety warning signs are displayed when the IPL equipment and laser are in use as described within the local rules.

Arrangements are in place to ensure that the IPL and laser keys are stored safely and securely when the equipment is not in use.

A laser protection report prepared by Dr Ian Gillan, RQIA's medical physics advisor has been appended to this report and also outlines any deficits in laser safety arrangements within the establishment.

One requirement and three recommendations were made as a result of the variation inspection, details can be found in the main body of the report and the attached Quality Improvement Plan (QIP).

Overall the establishment was found to be providing a safe and effective service; laser safety arrangements are generally of a high standard.

The inspector wishes to thank Ms Jenny Flanagan for her helpful discussions, assistance and hospitality throughout the inspection process.

7.0 Inspection Findings

7.1 Statement of purpose and Patient Guide

A Statement of Purpose and Patient Guide were in place in line with the Independent Health Care Regulations (Northern Ireland) 2005. It is recommended that both documents are updated to reflect the additional IPL treatments which will be offered by the establishment.

7.2 Client Partnerships

There are robust systems already in place to obtain the views of clients on the quality of laser treatments, information and care received. Miss Flanagan confirmed that this will be extended to include clients receiving IPL treatments.

A copy of the summary report is made available to patients and other interested parties.

7.3 Complaints

The establishment operates a complaints policy and procedure in accordance with the Department of Health, Social Services and Public Safety (DHSSPS) guidance on complaints handling in regulated establishments and agencies (April 2009) and the Independent Health Care Regulations (Northern Ireland) 2005. Staff spoken with demonstrated an understanding of complaints management.

Systems are in place to effectively document and manage complaints.

7.4 Staff Training and Development and Training for Staff using Lasers and Intense Light Sources

A record of training was available for the authorised user, Ms Flanagan.

Core of knowledge training was undertaken in September 2013.

The safe use and application of the IPL equipment training was undertaken on 19 June 2015.

A review of the training records confirmed that all mandatory training outlined in the RQIA guidance had been completed.

Laser safety awareness training has been provided for staff not directly involved in the use of the IPL equipment and laser.

7.5 Infection Prevention and Control

The establishment has policies and procedures in place for infection prevention and control.

The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor.

Ms Flanagan had received training in infection prevention and control on 29 January 2015.

Cleaning schedules were in place and arrangements for the decontamination of equipment between clients.

The establishment had hand washing facilities available within the treatment room.

There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available.

7.6 Client Information and IPL Procedures

The establishment has policies and procedures for advertising and marketing which are factual and not misleading. Advertisements do not offer discounts linked to a deadline for booking appointments. Promotional events do not include financial incentives for potential clients to book a consultation at the event.

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

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 treatment 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 GP, with their consent, for further information if necessary.

7.9 Procedures for the User of Lasers and Intense Light Sources

Agreed medical treatment protocols for the laser were in place.

Ms Flanagan had protocols developed by the manufacturer of the IPL equipment.

A requirement was made to develop medical treatment protocols for the IPL equipment which 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

The medical treatment protocols should be agreed and signed by the medical practitioner providing medical support services. Systems should be in place to review the protocols for both laser and IPL equipment on an annual basis.

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

The establishment has local rules in place which have been developed by their LPA in June 2015.

Systems are in place to review the local rules every annually.

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 LPA has visited the establishment in March 2015; however there was no record of the visit available. It is recommended that the LPA should provide a report of his findings at each visit or the clinic retains a log which the LPA signs and dates. The inspector advised retaining a copy of any ongoing correspondence with the LPA e.g. emails and phone calls.

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

Ms Flanagan is the only authorised user of the laser and IPL equipment and a register of authorised users is maintained.

Ms Flanagan has signed to state that she has read and understood the local rules and medical treatment protocols.

A register will be maintained for every time the IPL is operated and includes:

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

The existing laser register was reviewed and found to contain all of the information required by legislation.

The proposed client care records for IPL treatments were reviewed and found to contain a health questionnaire, consent form and record of treatment.

7.10 Safe Operation of Lasers and Intense Light Sources

The environment in which the IPL equipment and laser is 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 the LPS.

A risk assessment had been undertaken by the LPA dated June 2015.

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

Protective eyewear was available for the client and operator. However, the local rules refer to the use of “disposable IPL aids” to be worn by patients instead of “disposable laser aids”. It is recommended that the LPA corrects the local rules to reflect the protective eyewear available within the establishment.

Entrance doors are locked when the laser and IPL equipment is in use. Arrangements are in place to enable access to the locked room in the event of an emergency.

There are formal written arrangements in place for the safe custody of the laser and IPL keys. The IPL equipment and laser key was observed to be stored safely and securely during the inspection.

There is a laser safety file in place.

Equipment is serviced and maintained in line with the manufacturers’ guidance. The most recent service reports were reviewed as part of the inspection process.

8.0 Laser Protection Report

A laser protection report prepared by Dr Ian Gillan, RQIA’s medical physics expert has been appended to this report and outlines any deficits in laser safety arrangements within the establishment.

9.0 Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Ms Jenny Flanagan, authorised user, as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

9.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered persons meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

9.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments. They promote current good practice and if adopted by the registered person may enhance service, quality and delivery.

9.3 Actions Taken by the Registered Manager/Registered Person

The QIP should be completed by the registered person/registered manager and detail the actions taken to meet the legislative requirements stated. The registered person will review and approve the QIP to confirm that these actions have been completed. Once fully completed, the QIP will be returned to independent.healthcare@rqia.org.uk and assessed by the inspector.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the establishment. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person/manager with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the establishment.

Quality Improvement Plan

Statutory Requirements

Requirement 1 The registered manager must ensure that medical treatment protocols are developed as outlined in the main body of the report.

Ref: Regulation 39 (2)

Stated: First time

To be Completed by:
28 September 2015

Response by Registered Person(s) Detailing the Actions Taken:
Appointed EMP (expert medical practitioner) Dr Donal McKeown has signed off medical treatment protocols.

Recommendations

Recommendation 1 It is recommended that the Statement of Purpose and Patient Guide are updated to include the IPL treatments offered by the establishment.

Ref: Standard 16.7 & 16.8

Stated: First time

To be Completed by:
28 September 2015

Response by Registered Person(s) Detailing the Actions Taken:
The statement of purpose and patient guide have both been updated to include IPL treatments offered.

Recommendation 2 It is recommended that the LPA correctly identifies the disposable eye protection available within the establishment and amends the local rules accordingly.

Ref: Standard 48.17

Stated: First time

To be Completed by:
28 September 2015

Response by Registered Person(s) Detailing the Actions Taken:
LPA Alex Zameh ammended the local rulesto include disposableIPL eye shields.

Recommendation 3 It is recommended that the LPA provides a report of his findings at each visit or signs a log retained within the clinic. Evidence of all ongoing correspondence with the LPA should also be retained.

Ref: Standard 48.6

Stated: First time

To be Completed by:
28 September 2015

Response by Registered Person(s) Detailing the Actions Taken:
Proof of LPA Alex Zamehs visit with an onsite visit report included.

Registered Manager Completing QIP	Sheila Jordan	Date Completed	22/10/2015
Registered Person Approving QIP	Stephen Sinclair	Date Approved	22/10/2015
RQIA Inspector Assessing Response	Jo Browne	Date Approved	23/10/2015

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