Announced Care Inspection Report
29 & 30 August 2017

Optilase Therapie

Type of Service: Independent Hospital (IH) – Refractive Laser Eye Surgery and Dermatological Laser/Intense Pulsed Light (IPL) Service
Address: Unit 4, Cleaver House, Donegall Place, Belfast BT1 5BB
Tel No: 02890438397
Inspectors: Winifred Maguire and Stephen O'Connor
RQIA's Medical Physics Advisor: Dr Ian Gillan

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) providing refractive laser eye surgery and a dermatological laser service. Mr Philip McGlade has submitted an application to RQIA as responsible individual which is currently being processed. Following the inspection, Ms Emma McFarlane requested an application as registered manager and RQIA awaits its submission.

The laser services are provided in two distinct categories:

- Refractive laser eye surgery
- Dermatological laser service

Refractive Laser Eye Surgery

Laser Equipment

Manufacturer: Schwind A
Laser Class: Class 4
Model: Armaris 500E
Serial Number: M110

Manufacturer: Abbott Medical Systems (AMO)
Laser Class: Class 3B
Model: Intralase IFS Advanced Femtosecond
Serial Number: F50511-70169

Laser Protection Advisor (LPA): Alex T Zarneh

Laser Protection Supervisor (LPS): Lawrence Dowie
Lisa McDowell

Clinical authorised operator: Wayne Crew-Browne (Consultant Ophthalmologist)

Non clinical authorised operators: Lawrence Dowie, Lisa McDowell, Nicole Brown, Christine Duffy, Joenil Ong, Donna Thompson

Types of Treatment provided: Refractive laser eye surgery - Lasix and Lasex

Dermatological Laser Services

Laser Equipment

Manufacturer: Alma
Laser Class: Class 4
Model: Harmony XL
Serial Number: HXL01057

Manufacturer: ABC
Laser Class: Class 4
Model: Soprano Platinum
Wavelength: 755nm, 810nm, 1064nm
Serial Number: PLAT0380

Manufacturer: ABC
Laser Class: Class 4
Model: Soprano Platinum
Wavelength: 755nm, 810nm, 1064nm
Serial Number: PLAT0381

Manufacturer: ABC
Laser Class: Class 4
Model: Soprano Platinum
Wavelength: 755nm, 810nm, 1064nm
Serial Numbers: PLAT0382

Associated equipment

Equipment:	Plume evacuator
Manufacturer:	Quatro
Model:	Fresh Air 400
Serial number:	18461

Equipment:	Skin Cooler
Manufacturer:	ABC
Model:	Lasercryo air
Serial number:	110310483

Laser protection advisor (LPA): Alex Zarneh

Laser protection supervisor (LPS): Fionnuala McKenna and in her absence another named authorised operator

Medical support services: Dr Ross Martin

Authorised operators

Soprano Platinum laser: Michelle Connor, Emma Douglas, Nicola Nugent, Fionnuala McKenna, Niamh Quinn, Emma Ferris, Sorcha Mc Kenna, Wendy Irwin, Danielle Douglas, Caomihne Lee McVey

Harmony XL laser: Michelle Connor, Emma Douglas, Nicola Nugent, Fionnuala McKenna

Types of Treatment Provided

Soprano Platinum laser: Hair removal/reduction

Harmony XL laser: Skin resurfacing
Skin rejuvenation

3.0 Service details

Organisation/Registered Provider: Therapie Clinic Ltd **Responsible Individual:** Mr Phillip McGlade(registration pending)	**Registered Manager:** Ms Emma McFarlane –application not yet submitted
Person in charge at the time of inspection: Fionnuala Mc Kenna (dermatological service)29 August 2017 Donna Thompson (refractive laser eye service)30 August 2017	**Date manager registered:** As above
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers; PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources and PD private doctor	

4.0 Inspection summary

An announced inspection took place on 29 August 2017 from 09.50 to 16.30 and 30 August 2017 from 09.55 to 14.05.

Dr Ian Gillan, RQIA's Medical Physics Advisor accompanied the inspectors to review the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

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, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: patient safety in respect of staff training and development; recruitment; safeguarding; laser safety arrangements; the management of medical emergencies; and the environment. Other examples included: the management of the patients' care pathway; communication; records management and engagement to enhance the patients' experience.

Two areas requiring improvement were identified against the regulations in relation to removing the cracked pane of glass placed under and around the wash hand basin in laser room four,

and providing evidence that the Harmony XL machine has been serviced in accordance with manufacturer's instructions. Eight areas requiring improvement were identified against the standards in relation to amending the infection prevention control policy for the refractive laser eye service to reflect practice; updating the practising privileges policy to reflect Northern Ireland legislation; re-establishing a staff register; providing staff not directly involved in the laser services with laser safety awareness training; providing specific information in the local rules on the protective eyewear for the Soprano Platinum and the Harmony XL laser machines; ensuring the area under the couches in the dermatological laser rooms are cleaned in accordance to cleaning schedules; ensuring client records for the dermatological laser service are fully and accurately completed; and ensuring a current fixed electrical wiring certificate is available for inspection.

Patients and clients who submitted questionnaire responses indicated that they were either very satisfied or satisfied with the services provided in Optilase Therapie.

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

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	2	8

Details of the Quality Improvement Plan (QIP) were discussed with Ms Fionnuala Mc Kenna, Therapie service manager and Ms Donna Thompson, Optilase service manager as part of the inspection process. The timescales for completion commence from the date of inspection.

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

4.2 Action/enforcement taken following the most recent care inspection dated 30-31 August 2016

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 30-31 August 2016.

5.0 How we inspect

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

- notifiable events since the previous care inspection
- duty calls
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the returned QIP from the previous care inspection
- the previous care inspection report
- submitted complaints declaration

Questionnaires were provided to patients, clients and staff prior to the inspection by the establishment on behalf of RQIA. Returned completed patients, clients and staff questionnaires were also analysed prior to the inspection.

A poster informing patients and clients that an inspection was being conducted was displayed.

During the inspection, the inspector met with Mr Phillip McGlade, responsible individual applicant; Ms Fionnuala McKenna, Therapie service manager; Ms Donna Thompson, Optilase service manager; Ms Emma McFarlane, registered manager applicant; a laser technician for the refractive eye surgery; a laser scrub nurse; and two authorised operators for the dermatological laser service.

The following records were examined during the inspection:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- information provision
- care pathway
- management and governance arrangements
- practising privileges
- maintenance arrangements

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 the person in charge at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 30-31 August 2016

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 30-31 August 2016

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref**: Standard 3 **Stated:** First time	Revise the policy and procedure for adult protection in accordance with the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015) and ensure all staff sign to confirm they have read and understood the policy.	**Met**
	Action taken as confirmed during the inspection: The Adult safeguarding policy was reviewed and found to be largely in accordance with the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015). Further minor amendments were carried out during the inspection. Staff had signed to confirm that they had read and understood the policy.	
Area for improvement 2 **Ref**: Standard 48 **Stated:** First time	The current consultant ophthalmologists should devise the medical treatment protocols for refractive laser eye surgery.	**Met**
	Action taken as confirmed during the inspection: The medical treatment protocols for refractive laser eye surgery have been devised by the Mr Crewe – Brown, consultant ophthalmologist.	
Area for improvement 3 **Ref**: Standard 48 **Stated:** First time	The medical treatment protocols should be amended to be in accordance with the treatments provided in the establishment using the Harmony XL machine.	**Met**
	Action taken as confirmed during the inspection: The medical treatment protocols for the Harmony XL machine have the laser treatments highlighted that are provided in the establishment using this laser machine.	

Area for improvement 4 **Ref**: Standard 48 **Stated:** First time	The LPS on duty for the dermatological laser service should be clearly identified and other authorised operators should be aware of who the LPS on duty is.	**Met**
	Action taken as confirmed during the inspection: The LPS on duty for the dermatological laser service is Ms Fionnuala McKenna and in her absence there is a nominated named authorised operator. Staff spoken to were aware of these arrangements.	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Discussion with management and staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment; patients and clients. This includes a team of: a consultant ophthalmologist; an optometrist; laser scrub nurses; and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery. The dermatological laser service is staffed separately by 11 authorised operators.

It was confirmed that refractive laser eye procedures are only carried out by a trained medical practitioner acting as clinical authorised operator, and laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the lasers is maintained and kept up to date in respect of the refractive laser eye surgery service. A register of authorised operators is also maintained for the dermatological laser service.

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 all authorised operators have up to date training in core of knowledge training; application training for the equipment in use; basic life support; infection prevention and control; and fire safety.

There was no evidence that all other staff employed at the establishment, but not directly involved in the use of the laser equipment, have received laser safety awareness training. An area of improvement was identified against the standards on this matter.

Evidence was available that confirms that staff who have professional registration undertake continuing professional development (CPD), in accordance with their professional body's recommendations.

An electronic staff register had previously been in place; however, on discussion it was confirmed it could not be accessed following the departure of the previous responsible individual. An area of improvement was identified against the standards on this matter.

Discussion with staff and review of documentation confirmed that there are systems in place for undertaking, recording and monitoring all aspects of staff supervision and ongoing professional development for staff. Staff appraisal had been undertaken in respect of some staff and it was confirmed staff appraisal for all other staff has been arranged to be undertaken in the coming weeks.

A review of a consultant ophthalmologist's details confirmed there was evidence of the following:

- confirmation of identity
- current General Medical Council (GMC) registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer
- arrangements for revalidation

Recruitment and selection

A review of ten personnel files of authorised operators recruited since the previous inspection and discussion with management confirmed that new staff have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Safeguarding

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. Staff were aware of who the nominated safeguarding lead was within the establishment.

Review of records demonstrated that all staff in the establishment had received training in safeguarding adults. However, on review, it pertained to the English legislation. Following the inspection it was confirmed that adult safeguarding training in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) had been arranged and staff were in the process of completing the training.

Policies and procedures were in place for the safeguarding and protection of adults 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 for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included. Minor amendments were made to the policy during the inspection.

Laser/IPL safety

The refractive laser eye surgery service

A laser safety file was in place which contained all of 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 in July 2018.

Refractive eye surgical procedures are carried out by a trained medical practitioner in accordance with medical treatment protocols devised by the consultant ophthalmologist.

Up to date local rules were in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used. The local rules were amended following the inspection to outline more detail in relation to the laser warning signage including an image, laser warning lights, laser protective eyewear and the safe storage of the laser keys. A copy of the amended local rules was forwarded to RQIA following the inspection.

The establishment's LPA completed a risk assessment of the premises in June 2017 and any recommendations made were addressed.

A list of clinical and non-clinical authorised operators was maintained and all authorised operators have signed to state that they have read and understood the local rules.

When the laser equipment is in use for the refractive laser eye surgery service, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to fulfil the role. Discussion with staff confirmed that systems are in place to ensure other authorised operators are aware who the LPS on duty is.

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 controlled area is clearly defined and not used for other purposes, or as access to areas, when surgery is being carried out. A keypad lock on the connecting door from the pre-operative waiting room and the laser suite was found to be broken. However, it was repaired during the inspection.

The doors to the laser suite are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using keys and passwords. Arrangements were in place for the safe custody of the laser keys when not in use and passwords are only known by authorised operators.

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

Protective eyewear was available for laser technicians if required, as outlined in the local rules, which were amended following the inspection to be more specific in relation to this matter.

The establishment has a laser surgical register 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

A review of the laser surgical register during the inspection found it to be comprehensively completed.

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

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

The dermatological laser service

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Ross Martin and due for review in 2018. Systems are in place to review the medical treatment protocols on an annual basis.

Up to date local rules were in place which have been developed by the LPA. The local rules contained most of the relevant information pertaining to the laser equipment being used. The protective eyewear information relating to each laser machine was found to be generic. It was difficult to clearly ascertain the specific type of protective eyewear recommended for each machine, particularly as the Soprano Platinum laser machines had a range of wavelengths and the Harmony XL machine had four heads, each providing treatment at a different wavelength. It was noted that one set of protective eyewear goggles, labelled for a specific machine, did not have the wavelengths, for which the laser machine provided treatments at ,listed on them. As stated, the local rules provided generic information and therefore it was not possible to match the protective eyewear provided to the information outlined in the local rules. This set of protective eye wear was removed from use immediately and replaced by protective eyewear listing all the relevant wavelengths. An area of improvement against the standards was identified in relation to ensuring the local rules outline specific information on protective eyewear.

All protective eyewear was clearly labelled for use.

The establishment's LPA completed a risk assessment of the premises in June 2017 and no recommendations were made.

Authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser equipment is in use for the dermatological laser service, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to

fulfil the role. Discussion with staff confirmed that systems are in place to ensure other authorised operators are aware who the LPS on duty is.

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 rooms are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using keys. The laser keys were noted to be stored in a plastic box in each treatment room. This arrangement was deemed unsuitable for the safe custody of the laser keys when not in use. Immediately, management reviewed the arrangements for the safe custody of the laser keys and it was confirmed the laser keys are kept in a locked area, and a laser key log outlining the signing in and out of the laser keys by authorised operators only is in operation.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use. Staff were reminded of the importance of this on inspection.

The establishment has a laser register for each laser 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

Three new Soprano Platinum machines have been installed since the previous inspection. Installation reports were available for each of these machines and arrangements for their ongoing servicing and maintenance are in place.

The Harmony XL laser machine did not have evidence that it had been maintained and serviced in accordance with manufacturer's instructions. An area of improvement against the regulations has been identified on this matter.

Management of emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment.

The policy on managing a medical emergency was in place. Minor amendments were made to the policy during inspection and it was found to provide clear instructions on what to do in the event of a medical emergency.

Infection Prevention and Control and Decontamination Procedures

There were clear lines of accountability for infection prevention and control (IPC) in place.

A range of information was available for patients, clients and staff regarding hand washing techniques.

Arrangements were in place to ensure the decontamination of equipment and reusable medical devices are in line with manufacturer's instructions and current best practice. Staff confirmed single use equipment is used where possible. Theatre sterile packs are provided from an accredited organisation.

Staff have been provided with IPC training commensurate with their role.

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits have been carried out including:

- environmental
- hand hygiene
- post treatment infection

The compliance rate was noted to be good and an action plan was in place for areas of non-compliance.

IPC policies and procedures previously available were no longer in place. An IPC policy was in place and on review it was found to not adequately reflect the IPC arrangements for the refractive laser eye surgery service as outlined during staff discussion.

An area of improvement against the standards was identified on this matter.

There were completed cleaning schedules in place for the dermatological laser service. However, review of the dermatological laser rooms noted that there was dust underneath the client treatment couches. An area of improvement against the standards was identified on this matter.

Environment

The premises were maintained to a good standard of maintenance and décor.

Carbon dioxide (CO_2) fire extinguishers were available, which had been serviced within the last year.

Arrangements are in place for maintaining the environment. A legionella risk assessment has been undertaken and water temperature is monitored and recorded as recommended. A fire risk assessment had been undertaken and staff confirmed fire training and fire drills had been completed. Staff demonstrated that they were aware of the action to take in the event of a fire. A fixed electrical wiring certificate was not available for review. An area of improvement against the standards was identified on this matter.

It was noted in laser room '4' that a pane of glass placed underneath the base of the wash hand basin area had several cracks in it. An area of improvement against the regulations was identified to remove this broken pane of glass.

Patient, client and staff views

Eleven patients and clients submitted questionnaire responses. All indicated that they felt safe and protected from harm. Seven clients and patients indicated they were very satisfied with this aspect of care and four indicated that they were satisfied.

Comments provided included the following:

- "Happy with my treatment plan."
- "Staff very reassuring."

Eight staff submitted questionnaire responses. All indicated that they felt that clients are safe and protected from harm and that they were very satisfied with this aspect of care. Staff spoken with during the inspection concurred with this. The following comment was provided:

- "Therapists are highly trained and training is ongoing."

Areas of good practice

There were examples of good practice found throughout the inspection in relation to: staff recruitment; induction; training; supervision and appraisal; adult safeguarding; laser safety; management of emergencies; risk management and the environment.

Areas for improvement

All staff employed at the establishment, but not directly involved in the use of the laser equipment, should receive laser safety awareness training and a record maintained of the training.

An electronic staff register should be re-established.

The local rules in relation to the laser equipment used in the dermatological laser service should outline specific information on the protective eyewear.

The Harmony XL laser machine should be maintained and serviced in accordance with manufacturer's instructions and a record retained for inspection.

IPC policies and procedures should be in place which adequately reflects the IPC arrangements for the refractive laser eye surgery service.

The dermatological laser rooms should be cleaned in line with cleaning schedules including underneath the client treatment couches.

A current fixed electrical wiring certificate should be available for inspection.

Remove the broken pane of glass placed underneath the wash hand basin in laser room '4'.

	Regulations	Standards
Total number of areas for improvement	2	6

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Refractive laser eye surgery

Patients have an initial consultation with a qualified optometrist who discusses their treatment options and the cost of the surgery.

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

The establishment has a list of fees available for each type of surgical procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

It was confirmed that in accordance to GMC and the Royal College of Ophthalmologists guidance, patients meet with their surgeon on a separate day in advance of surgery, to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery to complete the consent process for surgery.

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

Patients are provided with clear post-operative instructions along with contact details for a senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Six patient care records were reviewed. The establishment retains hard copy care records which are supplemented with an electronic record system. The patient care records were well documented, contemporaneous and clearly outlined the patient journey. The care records reviewed contained the following.

- patient details
- medical history
- signed consent form
- initial consultation
- pre-operative notes

- intra-operative notes
- post-operative notes
- review/follow up notes

Dermatological laser service

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment has a list of fees available for each laser 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, with their consent, for further information if necessary.

Five client care records were reviewed. Most provided an accurate and up to date treatment record for every client which included:

- 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)

It was noted that one client record did not have the laser treatment provided fully outlined and another client record did not have the signature of the authorised operator providing the treatment recorded.

An area of improvement against the standards has been identified on this matter.

Records management

Observations made evidenced that patient and client records are securely stored.

Systems were in place to audit the completion of clinical records and an action plan is developed to address any identified issues. The outcome of the audit is reviewed through the establishment's clinical governance structures.

Information was available for patients and clients on how to access their health records, under the Data Protection Act 1998.

A review of documentation confirmed that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

The establishment is registered with the Information Commissioners Office (ICO).

Communication

As discussed, there was written information for patients and 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 establishment has a policy for advertising and marketing which is in line with legislation. .

Staff confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the establishment.

Patient, client and staff views

All patients and clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. Seven clients and patients indicated that they were very satisfied with this aspect of care and four indicated that they were satisfied. The following comment was provided:

- "Results are good so far."

Eight submitted staff questionnaire responses indicated that they felt that clients get the right care, at the right time and with the best outcome for them, and indicated that they were very satisfied with this aspect of care. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found in relation to the completion of clinical records for the refractive laser surgery service, the arrangements for records management and ensuring effective communication between patients, clients and staff.

Areas for improvement

Client records for the dermatological laser service should be fully and accurately completed.

	Regulations	Standards
Total number of areas for improvement	0	1

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with staff regarding the consultation and treatment or surgery confirmed that patients' and clients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient, client and the optometrist or authorised operator. Laser surgery is provided within a designated laser suite.

Information is provided to the patient and client in verbal and written form at all consultations to allow the patient and client to make choices about their care and treatment and provide informed consent.

Patients meet with the surgeon on a separate day in advance of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Appropriate measures are in place to maintain patient and client confidentiality; and observations made evidenced that care records were stored securely in locked filing cabinets and electronic records are password protected.

Separate patient and client satisfaction surveys are carried out by the establishment on an monthly basis and the results of these are collated to provide a monthly summary report which is made available to patients, clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires for the refractive laser eye surgery service found that patients were satisfied with the quality of treatment, information and care received. Some comments from patients included:

- "Made to feel at ease and supported throughout the treatment."
- "Great job, I am so happy with everything especially the result so far."
- "Very professional team who reassured me every step of the way."
- "Always reminded about an upcoming appointment."
- "Felt very accommodated during each stage of the process."
- "I would recommend your service, very helpful staff."

Review of completed client questionnaires for the dermatological laser service, found that there were no written comments and the service was rated 0-5. Whilst there was a high rating noted; the information relating to these ratings was limited. It was suggested to review the client survey to better capture meaningful information which could be used to drive improvement.

Patient, client and staff views

All patients and clients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care. Six clients and patients indicated that they were very satisfied with this aspect of care and five indicated that they were satisfied. The following comment was provided:

- "Staff were professional."

All submitted staff questionnaire responses indicated that they felt that clients and patients are treated with dignity and respect and are involved in decision making affecting their care, and indicated that they were very satisfied with this aspect of care. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining patient and client confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients and clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment, and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Ms Mc Kenna has overall responsibility for the day to day management of the dermatological laser service, and Ms Thompson has overall responsibility for the day to day management of the refractive laser eye surgery service. Both Ms Mc Kenna and Ms Thompson had submitted individual registered manager applications to RQIA. On discussion it was confirmed that only one registered manager is required for the registered service, Optilase Therapie. Following inspection it was confirmed, in accordance to the organisational structure, that Ms Emma McFarlane regional manager for Optilase Therapie, who is based in the establishment, would submit an application for registered manager. The previous two applications from Ms McKenna and Ms Thompson were subsequently withdrawn.

Mr Phillip McGlade submitted an application to RQIA to become the responsible individual of Optilase Therapie and three other laser services: Therapie Clinic Ltd (Derry), Therapie Optilase (Ennskillen) and Therapie Opitlase (Newry). The relevant information, supporting documentation and appropriate fees accompanied the application.

Discussion with Mr McGlade evidenced that he had a clear understanding of his role and responsibilities as a registered person under the relevant legislation and minimum standards. The following issues were discussed:

- the statement of purpose
- the patient and client guide
- the management of complaints
- notification of untoward incidents to RQIA and other relevant bodies
- quality assurance measures to monitor and improve practice as appropriate
- protection of adults at risk of harm
- responsibilities under the Independent Health Care Regulations (Northern Ireland) 2005
- responsibilities under The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- responsibilities under the DHSSPS Minimum Care Standards for Independent Healthcare Establishments (July 2014)
- responsibilities under health and safety legislation
- responsibilities for the safe use and operation of the IPL and laser
- any court cases pending/disciplinary cases with employers/professional regulatory bodies

Registration of Mr McGlade with RQIA as registered person is recommended, pending receipt of an Enhanced AccessNI check.

Mr Mc Glade confirmed he will visit the establishment on weekly basis. He also confirmed that the establishment is moving premises in the coming months. Advice was given on this matter to ensure compliance with the regulations and best practice. RQIA have received a variation to registration in relation to the change of premises, which is currently being processed.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on annual basis. Staff spoken with were aware of the policies and how to access them.

It was demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Mr McGlade demonstrated an increased awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice.

It was confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was in place to ensure that urgent communications, safety alerts and notices are reviewed, and where appropriate made available to key staff in a timely manner.

It was confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. A monthly

audit is conducted and it was confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. The audit programme included the following:

- laser log completion
- laser goggles safety
- laser machine service records
- clinic policies/procedures
- cleaning schedules
- staff personnel files, training and certificates
- complaints
- patient and client files
- comment card completion

However, areas of improvement identified during this inspection would indicate that governance arrangements and the monitoring systems within the establishment need to be strengthened to provide more meaningful sustained improvement.

The process for granting practising privileges was outlined and it was confirmed medical practitioners will meet with the responsible individual prior to privileges being granted.

A medical practitioner's personnel file reviewed confirmed that there was a written agreement between the medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years.

A policy and procedure was in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges. It was noted there were references to English legislation. An area of improvement against the standards was identified on this matter.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

It was confirmed that the statement of purpose and the patient's and client's guides are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

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

Patient, client and staff views

All patients and clients who submitted questionnaire responses indicated that they felt that the service is well managed. Six clients and patients indicated that they were very satisfied with this aspect of care and five indicated that they were satisfied. The following comments were provided:

- "Staff were all very good and couldn't do enough for all the patients."
- "Staff very knowledgeable about treatments."

All submitted staff questionnaire responses indicated that they felt that the service is well led and indicated that they were very satisfied with this aspect of care. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to the management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

The policy and procedure for the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges should be amended to remove the reference to the English legislation.

	Regulations	Standards
Total number of areas for improvement	0	1

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Mc Kenna, Therapie service manager and Ms Thompson Optilase service manager as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified 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 the laser service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005; The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011; and the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP **via Web Portal** for assessment by the inspector.

RQIA will phase out the issue of draft reports via paperlite in the near future. Registered providers should ensure that their services are opted in for the receipt of reports via Web Portal. If you require further information, please visit www.rqia.org.uk/webportal or contact the web portal team in RQIA on 028 9051 7500.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref**: Regulation 15 (2) **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that the Harmony XL laser machine is maintained and serviced in accordance to manufacturer's instructions and a record retained for inspection. Ref: 6.4
	Response by registered person detailing the actions taken: Service agreement in place and reports are available
Area for improvement 2 **Ref:** Regulation 25 (2)d **Stated:** First time **To be completed by:** 30 August 2017	The registered person shall ensure the broken pane of glass placed underneath the wash hand basin in laser room '4' is removed. Ref: 6.4
	Response by registered person detailing the actions taken: Complete
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref**: Standard 48.13 **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that all staff employed at the establishment, but not directly involved in the use of the laser equipment, receives laser safety awareness training and a record is maintained of the training. Ref: 6.4
	Response by registered person detailing the actions taken: All staff have been trained and certified.

Area for improvement 2 **Ref**: Standard 12.5 **Stated:** First time **To be completed by:** 30 October 2017	The registered person shall ensure that an electronic staff register is re-established. Ref: 6.4
	Response by registered person detailing the actions taken: Complete and ongoing
Area for improvement 3 **Ref**: Standard 20.2 **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that IPC policies and procedures are in place which adequately reflects the IPC arrangements for the refractive laser eye surgery service. Ref: 6.4
	Response by registered person detailing the actions taken: IPC policies updated
Area for improvement 4 **Ref**: Standard 48.17 **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that the local rules in relation to the laser equipment used in the dermatological laser service should outline specific information on the protective eyewear. Ref: 6.4
	Response by registered person detailing the actions taken: Our LPA has amended the local rules
Area for improvement 5 **Ref**: Standard 22.11 **Stated:** First time **To be completed by:** 30 August 2017	The registered person shall ensure that the dermatological laser rooms are cleaned in line with cleaning schedules including underneath the client treatment couches. Ref: 6.4
	Response by registered person detailing the actions taken: Manager to carry out regular audits of treatmnet areas.
Area for improvement 6 **Ref**: Standard 22.3 **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that a current fixed electrical wiring certificate is available for inspection. Ref: 6.4
	Response by registered person detailing the actions taken: Fixed wiring works completed on 8/10/17, we await the report.

Area for improvement 7 **Ref**: Standard 48.10 **Stated:** First time **To be completed by:** 30 August 2017	The registered person shall ensure that client records for the dermatological laser service are fully and accurately completed. Ref: 6.5
	Response by registered person detailing the actions taken: Client record audits have been increased to 2 weekly.
Area for improvement 8 **Ref**: Standard 11.1 **Stated:** First time **To be completed by:** 30 September 2017	The registered person shall ensure that the policy and procedure for the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges is amended to remove reference to the English legislation. Ref: 6.7
	Response by registered person detailing the actions taken: Complete

Please ensure this document is completed in full and returned via Web Portal

*

31st August 2017

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

Dear Mrs Maguire

Laser Protection Report

Optilase ,Unit 4 - Cleaver House, Donegall Place, Belfast BT1 5BB

Optilase Inspection

Summary
The Laser safety arrangements remain at a high standard.

Introduction
Further to yesterday's inspection 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 current legislation, relevant guidance notes, European Standards and the Control of Artificial Optical Radiation at Work Regulations (Northern Ireland) 2010.

Deficiencies & Comments
Local Rules:- Although the current Local Rules are satisfactory there are several sections which could be developed to provide clearer instructions, in particular a review of the following aspects should be considered

(1) Information on which of the Laser Controlled Area signs is the 'approved' version. Perhaps an image of the sign could be placed in the local rules.
(2) A laser warning light is fitted at one of the entrance doors but is not referred to in the local rules. From discussions with staff this light is an indicator that a client is in the treatment room, so again this arrangement should be clarified.
(3) It would be normal practice for the LPA to detail the protection level of the required laser goggles within the local rules.
(4) The arrangement for safe storage of the laser keys is not clearly detailed in the local rules and does not reflect current practice.

As there are plans to relocate the service this would be an appropriate time to ensure that the above points are considered in any new facility.

Ian Gillan

Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Optilase ,Unit 4 - Cleaver House, Donegall Place, Belfast BT1 5BB

Laser Systems

Manufacturer:	Schwind
Model	Amaris 500E
Type	Excimer
Wavelength	193nm
Serial Number:	M110

Manufacturer:	Abbott Medical Systems (AMO)
Model	IFS Advanced Femtosecond
Type	Intralase
Wavelength	1053nm
Serial Number:	0511-70169

Laser Protection Adviser

Dr Alex Zarneh

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