

Announced Care Inspection Report 12 December 2019



Aesthetic Enhancement Ltd

**Type of Service: Independent Hospital (IH) –
Cosmetic Laser/Intense Pulse Light (IPL) Service**
**Address: 7B Messines Terrace, Racecourse Road, Londonderry,
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Tel No: 077 1189 0094
Inspector: Emily Campbell

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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

Aesthetic Enhancement Ltd is registered as an Independent Hospital (IH) with the following category of care: Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT(L) and /or establishments using intense light sources PT (IL). The establishment provides a range of cosmetic/aesthetic treatments. This inspection focused solely on those treatments using a Class 4 laser and an intense pulse light (IPL) machine that fall within regulated activity and the category of care for which the establishment is registered with RQIA.

The establishment was initially registered to provide treatment using an IPL machine. Since the previous inspection, an application for variation to registration was submitted to RQIA to provide treatments using a Class 4 laser PT(L). This was approved by RQIA on 31 July 2019.

Laser equipment:

Manufacturer: Cynosure
 Model: Elite ELM+
 Serial Number: ELM+2002
 Laser Class: 4
 Wavelength: 755nm Alexandrite
 1064nm Nd:YAG

IPL equipment:

Manufacturer: Ellipse Light
 Model: SP1
 Serial Number: 06040714
 Hand Pieces: VL-2, HR

Laser protection advisor (LPA):

Mr Alex Zarneh

Laser protection supervisor (LPS):

Ms Elaine McVeigh

Medical support services:

Dr Rupert Gabriel (for IPL treatments)
 Dr Paul Reddy (for laser treatments)

Authorised operator:

Ms Elaine McVeigh

Types of treatment provided:

- hair removal
- skin rejuvenation
- thread vein removal

3.0 Service details

Organisation/Registered Provider: Rocha Celeste Limited	Registered Manager: Ms Elaine McVeigh
Responsible Individual: Ms Elaine McVeigh	
Person in charge at the time of inspection: Ms Elaine McVeigh	Date manager registered: 26 September 2016
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources	

4.0 Inspection summary

An announced inspection took place on 12 December 2019 from 10:00 to 12:05.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DoH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The 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. The establishment was initially registered to provide treatment using an IPL machine. Since the previous inspection, an application for variation to registration was submitted to RQIA to provide treatments using a Class 4 laser PT(L). This was approved by RQIA on 31 July 2019.

Examples of good practice were evidence in all four domains. These included training, safeguarding, the management of medical emergencies, infection prevention and control, information provision, the care pathway, the management and governance and maintenance arrangements.

An area for improvement was made against the regulations to ensure the laser is compliant with European Standard EN 60825. Two areas for improvement against the standards were made in relation to service level agreements between the establishment and the laser protection advisor (LPA) and medical support services.

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

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	1	2

Details of the Quality Improvement Plan (QIP) were discussed with Ms Elaine McVeigh, registered person, 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 04 October 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 4 October 2018.

5.0 How we inspect

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

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

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned completed clients questionnaires were analysed prior to the inspection. No staff are employed in Aesthetic Enhancement Ltd therefore no staff questionnaires were provided to RQIA.

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

During the inspection the inspector met with Ms McVeigh.

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

- 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 Ms McVeigh at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 04 October 2018

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

6.2 Review of areas for improvement from the last care inspection dated 04 October 2018

Areas for improvement from the last care inspection		Validation of compliance
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		
Area for improvement 1 Ref: Regulation 39 (1) Stated: First time	The responsible individual must established arrangements to ensure that the medical treatment protocols are reviewed in keeping with the timeframes specified on the document. Confirmation that the medical treatment protocols have been reviewed by a named medical practitioner must be submitted to RQIA upon return of this Quality Improvement Plan (QIP).	Met
	Action taken as confirmed during the inspection: Documentary evidence was submitted to RQIA following the previous inspection which confirmed that the medical treatment protocols in respect of the IPL were reviewed and were valid to 14 July 2019.	

<p>Area for improvement 2</p> <p>Ref: Regulation 18 (2) (a)</p> <p>Stated: First time</p>	<p>The responsible individual must submit to RQIA upon return of this Quality Improvement Plan (QIP) training certificates to evidence that Ms McVeigh, as the authorised operator, has completed refresher training in the following areas:</p> <ul style="list-style-type: none"> ● core of knowledge ● basic life support ● infection prevention and control 	<p>Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>Documentary evidence was submitted to RQIA following the previous inspection which confirmed that training in the above areas had been completed.</p>		
<p>Area for improvement 3</p> <p>Ref: Regulation 15 (1) (b)</p> <p>Stated: First time</p>	<p>The responsible individual must submit to RQIA upon return of this Quality Improvement Plan (QIP) a copy of the service level agreement between Aesthetic Enhancement Ltd and the appointed laser protection advisor (LPA).</p>	<p>Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>Documentary evidence was submitted to RQIA following the previous inspection which confirmed that the service level agreement between Aesthetic Enhancement Ltd and the appointed LPA was valid to November 2019.</p>		
<p>Area for improvement 4</p> <p>Ref: Regulation 39 (1)</p> <p>Stated: First time</p>	<p>The responsible individual must submit to RQIA upon return of this Quality Improvement Plan (QIP) a copy of the service level agreement between Aesthetic Enhancement Ltd and the medical support officer (author of the medical treatment protocols).</p>	<p>Met</p>
<p>Action taken as confirmed during the inspection:</p> <p>Confirmation was received by RQIA that medical support services were provided in respect of the IPL valid to July 2019.</p>		

Area for improvement 5 Ref: Regulation 15 (1) (b) Stated: First time	The responsible individual must submit evidence to RQIA upon return of this Quality Improvement Plan (QIP) to confirm that the local rules have been reviewed by the appointed laser protection advisor.	Met
	Action taken as confirmed during the inspection: Documentary evidence was submitted to RQIA following the previous inspection which confirmed that the local rules had been reviewed by the LPA and were valid to November 2019.	
Area for improvement 6 Ref: Regulation 15 (1) (b) Stated: First time	The responsible individual must submit to RQIA upon return of this Quality Improvement Plan (QIP) a copy of the risk assessment undertaken by the laser protection advisor within the past three years. Any action points made within the risk assessment should be addressed.	Met
	Action taken as confirmed during the inspection: A copy of the LPA report and risk assessment was provided to RQIA following the previous inspection which confirmed this had been undertaken within the past three years.	

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

Ms McVeigh confirmed that laser and IPL treatments are carried out by her as the authorised operator. The register of authorised operators for the laser and IPL machines reflects that Ms McVeigh is the only authorised operator.

It was confirmed that if any new authorised operators were recruited they would be provided with induction training.

A review of training records evidenced that Ms McVeigh has 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.

Ms McVeigh is the only person who works in Aesthetic Enhancement Ltd, and she confirmed that should any support staff be employed in the future that they would receive laser safety awareness training.

Recruitment and selection

There have been no authorised operators recruited since the previous inspection. Ms McVeigh confirmed that should authorised operators be recruited in the future robust systems and processes will be developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

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

Safeguarding

It was confirmed that laser/IPL treatments are not provided to persons under the age of 18 years.

Ms McVeigh was 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 Ms McVeigh, 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 the Minimum Care Standards for Independent Healthcare Establishments July 2014.

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 for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

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 staff reference

Laser/IPL safety

A laser safety file was in place which contained the relevant information in relation to laser/IPL equipment.

Ms McVeigh confirmed that Mr Alex Zarneth is the appointed laser protection advisor (LPA) for Aesthetic Enhancement Ltd. However, there was no written confirmation of this. Documentary evidence was submitted to RQIA by email on 17 December 2019 confirming that Mr Zarneth was currently the LPA for the establishment, however, there was no date indicated of when the service level agreement expires. An area for improvement against the standards was made that evidence confirming the dates of the service level agreement between the establishment and the LPA should be submitted to RQIA and a copy retained in the laser protection file.

As discussed previously, an application for variation to registration to provide treatments using a Class 4 laser was approved by RQIA on 31 July 2019. It was noted that the labelling of the laser does not comply with the requirements of the European Standard EN 60825. This observable area of non-compliance indicates a failure by the manufacturer to meet the required European Standard; this may indicate that other aspects of relevant European standards may not have been complied with when achieving CE marking. An area for improvement against the regulations was made to raise this matter with the manufacturer and take the appropriate steps to address this issue. Advice and guidance should be sought from the LPA.

Ms McVeigh confirmed that laser/IPL procedures are carried out in accordance with medical treatment protocols. The medical treatment protocols contained the relevant information pertaining to the treatments being provided. Medical treatment protocols in respect of the laser were produced by Dr Paul Reddy and were valid to March 2022. However, the medical treatment protocols in respect of the IPL produced by Dr Rupert Gabriel, expired in July 2019. On 17 December 2019 Ms McVeigh provided RQIA with written confirmation from the LPA that the medical support officers had reviewed the medical treatment protocols and there were no changes, however, this was not confirmed in writing from authors of the medical support protocols. An area for improvement against the standards was made to provide RQIA with confirmation of the contracted dates of the medical support services; that the IPL medical treatment protocols have been reviewed and clearly state the current review date.

Local rules were in place in respect of the laser and IPL which have been developed by the LPA and contained the relevant information pertaining to the equipment being used. The local rules for the laser were valid to June 2020, however, the local rules for the IPL were valid to November 2019. On 17 December 2019 Ms McVeigh provided RQIA with written confirmation received from the LPA, which stated that there were no changes to the local rules in place.

The LPA had completed a risk assessment of the premises which was valid to June 2020 and Ms McVeigh confirmed that recommendations made by the LPA have been addressed.

Ms McVeigh, as the laser protection supervisor (LPS) and only authorised operator has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Ms McVeigh has signed to state that she has read and understood the local rules and medical treatment protocols.

When the laser/IPL 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/IPL 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/IPL equipment is in use but can be opened from the outside in the event of an emergency.

The laser is operated using a key and the IPL using a keypad code. Arrangements are in place for the safe custody of the key and keypad code when not in use. Protective eyewear is available for the client and 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. Ms McVeigh was advised that the laser safety warning sign should only be displayed when the laser/IPL equipment is in use and removed when not in use.

The establishment has a laser/IPL 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

The laser/IPL register has two distinct sections to differentiate between laser and IPL treatments.

There are arrangements in place to service and maintain the laser and IPL equipment in line with the manufacturer's guidance. The most recent service report of the IPL on 24 October 2019 was reviewed as part of the inspection process. Ms McVeigh confirmed that the recently purchased laser would be serviced annually.

Management of emergencies

Ms McVeigh had up to date training in basic life support and was aware of what action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

The treatment room was clean and clutter free. Discussion with Ms McVeigh 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, Ms McVeigh has up to date training in infection prevention and control.

Environment

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 in October 2019.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to training, adult safeguarding, management of emergencies, infection prevention and control, and the environment.

Areas for improvement

Evidence confirming the dates of the service level agreement between the establishment and the LPA should be submitted to RQIA and a copy retained in the laser protection file.

Confirmation should be provided to RQIA of the contracted dates of the medical support services; that the medical treatment protocols in respect of the IPL have been reviewed and clearly state the current review date.

The issue of noncompliance with EN 60825 should be raised with the laser manufacturer. Advice and guidance should be sought from the LPA in this regard.

	Regulations	Standards
Areas for improvement	1	2

6.5 Is care effective?

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

Care pathway

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/IPL 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.

Four client care records were reviewed. There is an accurate and up to date treatment record for every client which includes:

- 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 securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Communication

As discussed, 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 establishment has a policy for advertising and marketing which is in line with legislation.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records, and ensuring effective communication between clients and the authorised operator.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

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 Ms McVeigh regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is 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.

Client satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a summary report which is made available to clients and other interested parties. Ms McVeigh confirmed that an action plan would be developed to inform and improve services provided, if appropriate. Review of the most recent client satisfaction survey found that clients were highly satisfied with the quality of treatment, information and care received.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to 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.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
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

Ms McVeigh is the only authorised operator in this establishment.

Where the entity operating the establishment is a corporate body or partnership or an individual owner who is not in day to day management of the establishment, Regulation 26 unannounced quality monitoring visits must be undertaken and documented every six months. Ms McVeigh is in day to day charge of the practice, therefore Regulation 26 unannounced quality monitoring visits do not apply.

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

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

Ms McVeigh confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

Ms McVeigh demonstrated a clear understanding of her role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. Ms McVeigh confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was displayed, however, the certificate did not include the PT(L) category which was approved by RQIA in July 2019. Arrangements were made following the inspection for the up to date certificate to be issued to Ms McVeigh.

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

Areas of good practice

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

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 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 Ms McVeigh.

6.9 Client views

Six clients submitted questionnaire responses to RQIA. All indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All clients indicated that they were very satisfied with each of these areas of their care. One client provided a comment that they were very happy with the service provided.

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 McVeigh, registered person, 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 establishment. 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 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for 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.

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: 12 February 2020	The registered person shall raise the issue of noncompliance of the laser with European Standard EN 60825 with the laser manufacturer and take appropriate steps to address this matter. Advice and guidance should be sought from the laser protection advisor (LPA) in this regard. Ref: 6.4
	Response by registered person detailing the actions taken: I contacted my LPA and Cynosure. The sticker that was on the system apparently meets requirements. My inspector has been informed.
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)	
Area for improvement 1 Ref: Standard 48.6 Stated: First time To be completed by: 31 January 2020	The registered person shall submit on return of this QIP, evidence confirming the dates of the service level agreement between the establishment and the LPA. A copy of the service level agreement should be retained in the laser protection file. Ref: 6.4
	Response by registered person detailing the actions taken: My LPA has forwarded me a contract which has been signed and is in my folder.

<p>Area for improvement 2</p> <p>Ref: Standard 48.4</p> <p>Stated: First time</p> <p>To be completed by: 31 January 2020</p>	<p>The registered person shall provide to RQIA:</p> <ul style="list-style-type: none"> ● confirmation of the contracted dates of the medical support services ● confirmation that the IPL medical treatment protocols have been reviewed and clearly state the current review date <p>Ref: 6.4</p>
	<p>Response by registered person detailing the actions taken: My LPA has been advised on this matter. Confirmation of a medical support agreement has been forwarded to the Inspector. My LPA has also advised on the IPL Protocol Renewal and a review date. Confirmation has been sent to the Inspector.</p>

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



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