

Announced Variation Care Inspection Report 13 March 2017











Skinworkz Beauty Limited

Service Type: Independent Hospital

Sub Type: Cosmetic Laser

Address: 41a Bridge Street, Ballymena, BT43 5EL

Tel No: 07594165578 Inspector: Carmel McKeegan

1.0 Summary

An announced variation care inspection of Skinworkz Beauty Limited was carried out by Carmel McKeegan on 13 March 2017 from 10:30 to 11:45 the inspector was accompanied by Dr Ian Gillan, RQIA Medical Physics Advisor; the findings of Dr Gillan is appended to this report. Mr Colin Muldoon, estates inspector, also undertook a premises inspection on 13 March 2017 and the report and findings of the estates inspection are issued under separate cover.

An application was submitted to RQIA by Ms Karina Strojna, registered person, to vary the current registration of Skinworkz Beauty Limited. The establishment was initially registered on 02 September 2016 with a condition that registration was subject to confirmation of compliance with planning approval. The variation application was made to relocate the establishment to new premises.

The purpose of this announced variation inspection was to ascertain the progress to address the previous requirements and recommendations made as result of pre-registration inspections carried out on 18 and 29 July 2016 and assess the readiness of the new premises for the provision of a cosmetic laser service.

The variation to registration application was approved following this inspection.

Ms Karina Strojna, registered person and her business partner Mr Mark Leacock were available during the inspection and for verbal feedback at the conclusion of the inspection.

This inspection was underpinned by 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).

1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and	0	0
recommendations made at this inspection	U	U

This inspection resulted in no requirements or recommendations being made. Findings of the inspection were discussed with Ms Karina Strojna, registered person, and Mr Mark Leacock, business partner, as part of the inspection process and can be found in the main body of the report.

1.2 Actions/enforcement taken following the most recent inspection

Other than those actions detailed in the QIP there were no further actions required to be taken following the most recent inspections on 18 and 29 July 2016.

2.0 Service details

Registered organisation/registered person: Skinworkz Beauty Limited Ms Karina Strojna	Registered manager: Ms Karina Strojna
Person in charge at the time of inspection: Ms Karina Strojna	Date manager registered: 2 September 2016 (with condition)

Categories of care:

Independent Hospital (IH)

PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers

Laser Equipment

Manufacturer: Cynosure

Model: Affinity QS

Serial Number: QPA0138-0208

Laser Wavelength: 1064nm & 532nm

Laser Class: Class 4

Laser Protection Advisor (LPA)

Estelle Walker Onephoton Ltd

Medical Support Services

Dr Firas Al-Niaimi

Laser Protection Supervisor (LPS)

Mr Mark Leacock

Authorised Operator

Ms Karina Strojna

Type of Treatments Provided

Tattoo removal

3.0 Methods/processes

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

- review of the submitted variation to registration application
- discussion with Ms Ms Karina Strojna, registered person and Mr Mark Leacock
- assessment of the environment
- review of documentation required by legislation and good practice and
- evaluation and feedback

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated 18 and 29 July 2016

The most recent inspections of the establishment were announced pre-registration care and estates inspections which were both undertaken on 18 July 2016. The care inspection was completed on 29 July 2016. The completed Quality Improvement Plans (QIPs) were returned and approved by the care and estates inspectors. Following this, on receipt of outstanding information required in relation to estates issues, registration was approved, subject to confirmation of compliance with planning approval.

4.2 Review of requirements and recommendations from the last care inspection dated 18 and 29 July 2016

Last care inspection statutory requirements		Validation of compliance
Requirement 1	Policies and procedures for infection prevention and control must be developed and implemented.	
Ref: Regulation 15 (7)	Action taken as confirmed during the inspection: Review of records confirmed that an infection	Met
Stated: Second time	control policy and procedural guidance was in place.	
Requirement 2	The damaged protective laser operator eyewear should be replaced and comply with standard	
Ref: Regulation 39	EN207.	
Stated: First time	Action taken as confirmed during the inspection: Since the previous inspection a new laser has been provided and the previous laser has been removed.	Met
	Inspection of eyewear for the new laser machine confirmed that protective eyewear was available for the client and operator as outlined in the local rules compliant with standard EN207.	

Requirement 3	A record of the warranty period or alternatively	
	recommended arrangements for servicing the	
Ref: Regulation 39	Ultrapulse SMGH Serial No SMGH 12LE0901	
	should be provided in the laser safety file. A	
Stated: First time	copy should be provided to RQIA upon return of	
	this QIP.	Met
	Action taken as confirmed during the	INICL
	inspection:	
	As previously stated, a new laser has been	
	purchased and the Ultrapulse SMGH Serial No	
	SMGH 12LE0901 has been removed. A record of	
	the warranty period and servicing arrangements	
	was in place for the new laser.	
Requirement 4	The LPS (Mr Leacock) should notify the LPA that	
	the laser returned to the clinic from Ultrapulse in	
Ref: Regulation 39	July 2016 has a different serial number than the	
.	laser referred to in the LPA report dated 24	
Stated: First time	January 2016 and establish if a further laser safety	
	audit is required in this regard.	
		Met
	Confirmation of the outcome should be provided to	
	RQIA upon return of this QIP.	
	Action taken as confirmed during the inspection:	
	As previously stated the laser in question is no	
	longer provided in the establishment and the laser	
	protection advisor (LPA) has been notified that a	
	new laser is in place in the establishment.	
		Validation of
Last care inspection	recommendations	compliance
Recommendation 1	A policy for safeguarding adults at risk of harm	•
	should be developed and training undertaken.	
Ref: Standard 3	Action taken as confirmed during the	
	inspection:	Met
Stated: First time	The regional guidance document 'Adult	
	Safeguarding Prevention and Protection in	
	Partnership' (July 2015) was available for	
	reference.	
Recommendation 2	All records of maintenance and servicing of the	
	laser should be kept and filed in the laser safety	
Ref: Standard 48	file.	Met
6.	Action taken as confirmed during the	
Stated: First time	inspection:	
	A laser safety file was in place for the new laser	
	in accordance with best practice guidance.	

4.3 Inspection findings

4.3.1 Statement of purpose

A statement of purpose was prepared in a recognised format which covered the key areas and themes outlined in regulation 7, schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. The document had been updated to reflect the new address of the establishment.

4.3.2 Patient guide

A patient guide was available in a recognised format which covered the key areas and themes specified in regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005.

4.3.3 Recruitment of staff

The establishment does not employ any staff and Ms Strojna will be the only authorised operator of the laser. Ms Strojna is aware that if any new authorised operators are employed the information required under Regulation 19 (2) Schedule 2 of the Independent Healthcare Regulations (Northern Ireland) 2005 should be obtained and retained in personnel files. A recruitment procedure was in place which included all the information as stated in Regulation 19 (2).

4.3.4 Environment

The premises to be used for the provision of a cosmetic laser service were maintained to a good standard of maintenance and décor.

Colin Muldoon, estates inspector, reviewed the environment aspects of the establishment and the associated risk assessments as part of his inspection. The premises inspection report is issued under separate cover.

4.3.5 Staff training and development and training for staff using lasers and intense light sources

A record of training was available for both Ms Strojna and Mr Leacock. It had been established at the previous inspection that core of knowledge and the safe use and application training of the laser had been undertaken by Ms Strojna and Mr Leacock, however as a new laser machine has been provided both Ms Strojna and Mr Leacock have completed safe use and application training in relation to the new laser machine on 28 November 2016.

A record of training was available to confirm that Ms Strojna has completed training in basic life support, fire safety and infection prevention and control.

The regional guidance document 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) was available for reference and Ms Strojna confirmed that she was in the process of sourcing safeguarding training.

Other than Ms Strojna, there are no staff employed in the establishment. However Ms Strojna and Mr Leacock confirmed that in the event of staff being employed laser safety awareness training will be provided.

4.3.4 Infection prevention control

As previously stated, Ms Strojna has completed infection prevention and control training and an infection control procedural guidance has been provided.

The premises were clean and well maintained. Cleaning schedules were in place and arrangements for the decontamination of equipment between clients.

The establishment had hand washing facilities in a room adjacent to the treatment room.

There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available. Ms Strojna confirmed that a laminated hand washing poster would be provided and displayed above the wash hand basin. On 14 March 2017 RQIA received photographic verification that a laminated hand washing poster was displayed above the wash hand basin.

4.3.6 Procedures for the use of lasers and intense light sources

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Firas Al-Niaimi on 30 December 2016. Systems are in place to review the medical treatment protocols on an annual basis. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

The medical treatment protocols set out:

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

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

A risk assessment of the premises was undertaken by the LPA on 13 January 2017 and all issues identified have been addressed by the LPS.

The establishment has local rules in place which have been developed by their LPA on 24 January 2017 and systems are in place to review the local rules every year.

RQIA ID: 020087 Inspection ID: IN027498

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

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

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 establishment's LPA completed a risk assessment of the premises on 13 January 2017 and all recommendations made by the LPA have been addressed.

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

The establishment has a laser 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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service report of 21 November 2016 was reviewed as part of the inspection process.

4.3.6 Safe operations of lasers and intense light sources

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

When the equipment is in use, the safety of all persons in the controlled area is the responsibility of Ms Strojna.

Laser safety warning signs were in place and will be displayed when the 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 as outlined in the local rules.

The door to the treatment room will be locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

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

There is a laser safety file in place.

A carbon dioxide (CO2) extinguisher suitable for electrical fires was available in the controlled area of the establishment.

The inspector reviewed the incident policy and discussed the reporting of adverse incidents in line with the RQIA reporting procedure.

Employers and public liability insurance was in place valid to 20 February 2018.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0

5.0 Quality improvement plan

There were no issues identified during this inspection, and a QIP is neither required, nor included, as part of this inspection report.

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 registered provider from their responsibility for maintaining compliance with the regulations and standards.





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