

Announced Variation of Registration Care Inspection Report 2 March 2017



Cliffgar Dental Practice

**Service Type: Independent Hospital (IH) - Dental treatment, PT (L)
Prescribed Techniques or Technologies Laser services**

Address: 4 Newry Road, Banbridge, BT32 3HF

Tel No: 028 4066 2034

Inspector: Winnie Maguire

RQIA's Medical Physics Advisor: Dr Ian Gillan

1.0 Summary

An application was submitted to RQIA by Dr David Little in respect of Cliffgar Dental Practice for variation of registration to include prescribed techniques or technologies: establishments using Class 3b or Class 4 laser.

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

The inspection was carried out by Mrs Winnie Maguire on 2 March 2017 between the hours of 9.45 and 12.00. The inspector was accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor; the findings and report of Dr Gillan is appended to this report. Mr Kieran Monaghan estates inspector undertook a pre-registration premises inspection on the same day. The report and findings of the premises inspection will be issued under separate cover.

Dr David Little was available during the inspection and for verbal feedback at the conclusion of the inspection.

The dental practice is registered with RQIA and an announced inspection in relation to the dental service was carried out in October 2016, when no requirements and recommendations were made. This inspection focused on the dental practice's proposal to provide laser services.

During the course of the inspection the inspector discussed operational issues, examined a selection of records and carried out a general inspection of the establishment in respect of the proposed laser service.

A review of training records confirmed that authorised users had completed the required mandatory training. Dr Little confirmed staff not involved in the use of the Laser had received laser safety awareness training however there was no formal record of this training. A recommendation was made on this matter.

There was a policy and procedure in place for infection prevention and control. A recommendation was made to devise cleaning schedules which outline suitable arrangements for the decontamination of the laser equipment between patients including the protective eyewear.

It was confirmed that the treatment to be provided, fees, risks, complications and expected outcomes will be discussed with the patient during the initial consultation. Aftercare instructions will also be provided following treatment.

Dr Little confirmed patient laser treatments will be recorded on patient dental care records. Records will be retained in manual format and appropriate systems and processes are in place for the management of records and maintaining patient confidentiality.

The practice has dental laser treatment protocols in place written by Dr David Little in February 2017. Dr Little confirmed if children were to be treated with the laser then appropriate paediatric laser treatment protocols would be devised.

The practice has local rules developed by their laser protection advisor (LPA) and written on September 2013.

A risk assessment of the premises was undertaken by the LPA on 25 October 2013. A report of the last visit September 2013 by the LPA was available for inspection. It highlighted a range of issues for action. It was noted the written confirmation of appointment of the LPA had expired in on 30 September 2014. A recommendation was made to re-appoint a LPA. A further recommendation was made to arrange the LPA to re-visit the premises, update the laser documentation, review the issues highlighted in the LPA report and risk assessment. The updated laser documentation should be submitted to RQIA together with confirmation all issues within the LPA report and risk assessment have been addressed.

There was list of authorised users in place. The practice has not established a laser register. Advice was provided on this matter and a requirement was made to establish a laser register.

The environment in which the laser was used was found to be safe and controlled. Protective eyewear was available for the patient, the authorised user and the laser assistant as outlined in the local rules. A recommendation was made to label the laser protective eyewear for patient and staff use. Laser safety warning signs and lights will be displayed when the laser is in use as described within the local rules.

A requirement was made to establish servicing arrangements for the laser in accordance with manufacturer's instructions.

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, the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Standards for Dental Care and Treatment (2011) and the DHSSP Minimum Care Standards for Independent Healthcare Establishments (July 2014).

1.1 Inspection outcome

Information has been gathered throughout the registration process. Scrutiny of this information means that registration of this laser service is not recommended at this time. Significant elements within the matters set out above have been found to not yet be in place. These matters have been discussed with Dr David Little. Requirements and recommendations relating to these matters have been made in the inspection report. A timescale that has been agreed with Dr Little has been specified for submission to RQIA of a Quality Improvement Plan (QIP) addressing these matters.

Details of the QIP within this report were discussed with Dr David Little, registered person, as part of the inspection process. The timescales for completion commence from the date of inspection.

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	2	5

2.0 Service details

Registered organisation/registered person: Dr David Little	Registered manager: Dr David Little
Person in charge of the establishment at the time of inspection: Dr David Little	Date manager registered: 21 September 2011
Categories of care: Independent Hospital (IH) – Dental treatment PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers	

Laser equipment

Manufacturer: Biolase

Model: Epic 10

Serial Number: 640045274Z08

Laser Class: 4

Wavelength: 940nm +/- 10nm

Laser protection advisor (LPA)

Ms Estelle Walker

Laser protection supervisor (LPS)

Dr David Little

Authorised users

Dr David Little

Mr Andrew Little

Type of treatments provided:

Periodontal treatment designed to eradicate bacteria in the periodontal pocket and removal of diseased tissue

Excisional and incisional procedures

Canker sores, herpetic and aphthous ulcers of the oral mucosa

Low level laser therapy and teeth whitening

3.0 Methods/processes

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

- review of the submitted application forms and supporting documentation
- discussion with Dr David Little, registered person
- assessment of the environment
- review of documentation required by legislation and good practice
- evaluation and feedback

4.0 Inspection findings

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

A record of training was available for all authorised users.

Core of knowledge training was undertaken on 26 February 2017.

The safe use and application of the laser training was undertaken in 2013. Dr Little confirmed he was making arrangements for a dental practitioner, who is renowned in the field of lasers for use in dentistry, to visit the practice and observe the laser in use and offer advice.

Dr Little confirmed laser safety awareness training has been provided for staff not directly involved in the use of the laser, however there was no record of this training. A recommendation was made on this matter.

4.1.2 Infection prevention control

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

Staff have received training in infection prevention and control.

A recommendation was made to devise and implement cleaning schedules which outline suitable arrangements for the decontamination of laser equipment between patients including the protective eyewear.

The practice had hand washing facilities available within the surgery.

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

4.1.3 Patient information and laser procedures

Dr Little confirmed that patients will be provided with written information on the specific laser procedures that explains the risks, complications and expected outcomes of the treatment.

Patients will be provided with an opportunity to discuss their treatment and any concerns they may have.

The practice is registered with the Information Commissioner's Office.

4.1.4 Procedures for the use of lasers and intense light sources

Laser procedures will be carried out by trained operators in accordance with dental laser treatment protocols produced by Dr Little in February 2017.

Systems are in place to review the dental laser treatment protocols annually.

The dental laser 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

The written confirmation of the appointment and duties of a certified LPA had expired on 30 September 2014. A recommendation was made to re-appoint a LPA.

A risk assessment in relation to the use of a laser was undertaken by the LPA on 25 October 2013. The practice has local rules in place which have been developed by their LPA on September 2013.

The local rules cover:

- the potential hazards associated with lasers and intense light sources
- controlled and safe access
- authorised operators' responsibilities
- methods of safe working
- safety checks
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

The LPA report of the last visit in September 2013 was available for inspection. It highlighted a range of issues for action. A recommendation was made to arrange the LPA to re-visit the premises, update the laser documentation, review the issues highlighted in the LPA report and the risk assessment. The updated laser documentation should be submitted to RQIA together with written confirmation all issues within the LPA report and risk assessment have been addressed.

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

Laser operators are authorised to use the equipment and a register of authorised users is maintained.

Authorised users have signed to state that they have read and understood the local rules and dental laser treatment protocols.

A laser register had not yet been established. It is required that a laser register is established in line with the legislation to include the following:

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

Dr Little confirmed patient laser treatments will be recorded on patient dental care records. Records will be retained in manual format and appropriate systems and processes are in place for the management of records and maintaining patient confidentiality. The practice is registered with the ICO.

4.1.5 Safe operation 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 there is restricted 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 Dr David Little.

Laser safety warning signs and lights 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 patient, the authorised user and the laser assistant as outlined in the local rules. A recommendation was made to label the laser protective eyewear for patient and staff use.

The entrance doors to the surgery will be locked when the laser equipment is in use but can be opened from the outside in the event of an emergency. An access code is required to operate the laser which will only be known by the authorised users.

There is a laser safety file in place.

Arrangements have not yet been established for the equipment to be serviced and maintained in accordance with the manufacturers' instructions. A requirement has been made on this matter.

A carbon dioxide (CO₂) extinguisher suitable for electrical fires was available in the corridor outside of the surgery.

Areas for improvement

Make a formal record of laser safety awareness training provided to staff not directly involved in the use of the laser.

Devise and implement cleaning schedules which outline suitable arrangements for the decontamination of laser equipment between patients including the protective eyewear.

Re-appoint a laser protection advisor (LPA).

Arrange the LPA to re-visit the premises, update the laser documentation, review the issues highlighted in the LPA report and risk assessment. The updated laser documentation should be submitted to RQIA together with confirmation all issues within the LPA report and risk assessment have been addressed.

A laser register must be established in line with legislation.

Label the laser protective eyewear for patient and staff use.

Servicing arrangements for the laser must be established in accordance with manufacturer's instructions.

Number of requirements:	2	Number of recommendations:	5
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4.2 Laser protection report

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

5.0 Quality improvement plan

Any issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Dr David Little, registered person as part of the inspection process. The timescales commence from the date of inspection.

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

Matters to be addressed as a result of this inspection are set in the context of the current registration of the dental services. 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.

5.1 Statutory requirements

This section outlines the actions which must be taken so that the applicant meets legislative requirements based on The Independent Health Care Regulations (Northern Ireland) 2005.

5.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and DHSSPS Minimum Care Standards for Independent Healthcare Establishments (July 2014). They promote current good practice and if adopted by the registered provider may enhance service, quality and delivery.

5.3 Actions taken by the applicant

The QIP should be completed and detail the actions taken to meet the legislative requirements stated. The registered provider should confirm that these actions have been completed and return completed QIP to RQIA's office for review by the inspector.

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. It is expected that the requirements and recommendations outlined in this report will provide the registered provider with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

Quality Improvement Plan	
Statutory requirements	
Requirement 1 Ref: Regulation 39 Schedule 3(3) Stated: First time To be completed by: 2 May 2017	The registered provider must establish a laser register in line with legislation.
	Response by registered provider detailing the actions taken: Done as directed
Requirement 2 Ref: Regulation 15 (2) b Stated: First time To be completed by: 2 May 2017	The registered provider must establish servicing arrangements for the laser in accordance with manufacturer's instructions.
	Response by registered provider detailing the actions taken: Done
Recommendations	
Recommendation 1 Ref: Standard 48.13 Stated: First time To be completed by: 2 May 2017	Make a formal record of laser safety awareness training provided to staff not directly involved in the use of the laser.
	Response by registered provider detailing the actions taken: Lecture provided and handouts given to staff.
Recommendation 2 Ref: Standard 21.4 Stated: First time To be completed by: 2 May 2017	Devise and implement cleaning schedules which outline suitable arrangements for the decontamination of laser equipment between patients including the protective eyewear.
	Response by registered provider detailing the actions taken: Done and given to staff in writing
Recommendation 3 Ref: Standard 48.6 Stated: First time To be completed by: 2 April 2017	Re-appoint a laser protection advisor (LPA).
	Response by registered provider detailing the actions taken: Estelle Walker has been re- appointed and is continuing as LPA , she is reviewing all aspects.

<p>Recommendation 4</p> <p>Ref: Standard 48</p> <p>Stated: First time</p> <p>To be completed by: 2 May 2017</p>	<p>Arrange the LPA to re-visit the premises, update the laser documentation, review the issues highlighted in the LPA report and risk assessment. The updated laser documentation should be submitted to RQIA together with confirmation all issues within the LPA report and risk assessment have been addressed.</p> <p>Response by registered provider detailing the actions taken: All done</p>
<p>Recommendation 5</p> <p>Ref: Standard 48.17</p> <p>Stated: First time</p> <p>To be completed by: 2 May 2017</p>	<p>Label the laser protective eyewear for patient and staff use.</p> <p>Response by registered provider detailing the actions taken: All done</p>

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