Requirements for LIPLED

Employer's name:		**Date:**	
Modalities performed in this environment:			
Workplace address:		**Main contact: (Name & Tel No)**	

All lasers and IPLs must comply with current standards (e.g. BS EN 60601-2-22:2013 for medical lasers and BS 60601-2-57:2011 for IPL)

1	**Laser Protection**	**Yes/No**	**Evidence / comments**
A	Are roles & responsibilities of people operating on the premises clearly defined?		
B	Is there a named LPS/LSO appointed with roles & responsibilities clearly defined?		
C	Has the LPS/LSO had specific training for devices in use in addition to Core of Knowledge?		
	Does the appointed LPA hold current certification from a suitable awarding body?		
	Assessment of Standard 1:	**Met** ☐	**Part met** ☐ **Not met** ☐

2	**Authorised Users**	**Yes/No**	**Evidence / comments**
A	Have users had minimum training of a recognised/accredited Core of Knowledge taken within the last 5 years?		
B	Is there evidence of manufacturer or device specific training for each device and application?		
C	Is there a register of authorised users?		
D	Is there evidence of authorised users having read Local Rules?		
E	Is there evidence of certificates/training recorded & accurate?		
	Assessment of Standard 2:	**Met** ☐	**Part met** ☐ **Not met** ☐

3	Health and Safety	Yes/No	Evidence / comments
A	Has a laser/light device risk assessment been completed and appropriate for use?		
B	Is there evidence that risk assessments inform Local Rules & Facility File?		
C	Is there an eye and skin adverse incident policy & procedure and all stakeholders are aware of its contents?		
D	Are or will incidents be reported to the LPA and LPS if appropriate?		
E	Are or will all legally reportable accidents[1] incidents and ill-health be reported to the enforcing authority and will they be investigated to enable suitable remedial action to be taken?		
	Assessment of Standard 3:	**Met** ☐	**Part met** ☐ **Not met** ☐

4	Laser, Light Controlled Areas – clearly defined area	Yes/No	Evidence / comments
A	Is there A suitable entrance warning sign or light entry system which complies with Health and Safety (Safety and Signs and Signals Regulations 1996 and BS EN 60825-1?		
B	Are there suitable door locks or is there an interlock system installed?		
C	Are there laser proof blinds/barriers in place at windows, which block optical radiation, if indicated by the local rules?		
D	Is there a documented key control policy in place?		
E	Are there sink and handwashing facilities?		
F	Have reflective surfaces been identified and risk assessed?		
G	Have all ignition hazards been identified?		
H	Are there adequate extraction fans in place?		
I	Is there evidence of A device service agreement?		
K	Is appropriate eye protection in place based on the controlled area risk assessment?		

[1] Refer to RIDDOR http://www.hse.gov.uk/riddor/

L	Is there a documented lone policy worker policy in place?				
	Assessment of Standard 4:	**Met** ☐		**Part met** ☐	**Not met** ☐

5	**LIPLED Devices** need to be assessed against IEC 62471 (CIE S 009):2002	**Yes/No**	**Evidence / comments**		
A	Have devices been assessed against all of the following: • Aperture Label • Class/Max Power/ • Wavelength Label • Hazard Warning & • Precautions Label • Mains On Indicator • System On Indicator • Standby Mode Indicator • Emergency Off Switch • Capture Key Operation • Optical Safety Filters/Shutters				
	Assessment of Standard 5:	**Met** ☐		**Part met** ☐	**Not met** ☐

6	**Personal Protective Equipment** needs to be assessed against the following: • BS EN 207:2017 • BS EN 208:2009 • BS ISO 12609-1:2013 • BS ISO 12609-2:2013	**Yes/No**	**Evidence / comments**		
A	Has PPE been checked for the following: • Quantity • Make • For use by • Filter colour • Condition/cleanliness • Storage • CE marked • Eyewear covers full wavelength range - scale number e.g. 315-1400nm L7 (IR)				
	Assessment of Standard 6:	**Met** ☐		**Part met** ☐	**Not met** ☐

7	**Faculty Treatment Administration**	**Yes/No**	**Evidence / comments**
A	Are there accurate records of device, serial numbers, and intended treatments		

	for each device?		
B	Are there patient consent documents explaining the risks and benefits of procedures and accompanying aftercare information?		
C	Are there separate treatment protocols for each device approved by an ERHP? Which includes the following: • name and technical specification of equipment • contraindications • treatment technique – general • treatment technique – specific • client consent prior to treatment • cleanliness and infection control • pre-treatment tests • post-treatment care • recognition of treatment-related problems • emergency procedures • permitted variation on machine variables • procedure in the event of equipment failure		
D	Is there evidence of patient treatment records which are maintained to record the following each time the Laser/IPL is operated: • full name and DOB of the person treated • date of treatment • the operator's signature (this may be an electronic signature) • treatment given, including site and size of area, type of treatment; equipment and Laser/IPL parameters • any accidents or adverse effects		
	Is the register kept at premises to which it relates and is a bound hard copy with sequentially numbered pages including details of serial number and LIPLED device at the front?		
F	Are previous registers retained for 3 years?		
H	Is there evidence of Local Rules and the LPA assisted in the production of the local		

	rules. - LPA visited premises to produce local rules - Laser/IPL used only in accordance with local rules. Local rules include: • Assessment of risks associated with laser use. • Device description (including output, serial numbers etc). • Reference to treatment protocol. • Written procedures for safe use (including prevention of use by unauthorised persons; safe operation of device etc). • Adverse incident procedure including actions to be taken in cases of emergency (e.g. eye exposure and details of local A&E department). • Emergency shutdown procedure (as per manufacturer's manual or treatment protocol). • Details of LPA & LPS. • Register of Authorised Users - details of trained personnel with signed declarations of individuals that they have read and understood and will follow local rules at all times. • Laser/IPL operator training (requirements & certificates). • Controlled area designation and access • Operator responsibilities. • Protective eyewear (including when to be worn and minimum specification of protection). - Local rules kept in treatment room.				
I	Is there evidence the local rules are updated if there are any changes to the equipment, procedure or treatment room?				
J	Is there evidence of compliance with national and local legislation, guidance, standards?				
	Assessment of Standard 7:	**Met** ☐		**Part met** ☐	**Not met** ☐

8	Managing Complications	Yes/No	Evidence / comments		
A	Is there equipment in place to manage eye and skin injury, such as eye wash, eye patch or sterile gauze?				
B	Is there a documented policy, separate to the treatment protocol on managing complications. This should include a referral pathway in the event of an adverse reaction?				
C	Is there evidence of records kept of adverse reactions and lessons learned as a result of these?				
	Assessment of Standard 8:	**Met** ☐	**Part met** ☐	**Not met** ☐	

9	Advertising and Marketing	Yes/No	Evidence / comments		
A	Do adverts allow sufficient time between consultation and treatment in order for the client to consider consent?[2]				
B	Is factual information about LIPLED given in a balanced and factual manner?				
C	If images are used on the premises and/or the associated website are claims realistic about treatments outcomes?				
D	There are no promotional tactics, such as 'two-for-one' offers to encourage patients to make ill-considered decisions?				
E	Is advertising aimed at adults only and not targeted at teenagers below the age of eighteen?				
	Assessment of Standard 10 :	**Met** ☐	**Part met** ☐	**Not met** ☐	

[2] Refer to appropriate professional regulatory guidance. http://www.gmc-uk.org/guidance/ethical_guidance/28687.asp

Assessment Outcome:

Recommendation:	Accept ☐	Accept with action plan ☐	Reject ☐

Risk category:	High ☐	Medium ☐	Low ☐

The Employer or their representative:
(Please sign to agree that this is an accurate record of the assessment)

Signed:	Print name:	Job title:	Date:

Assessment Undertaken by:

Name:	Job title:	Date:

Quality assured by:

Name:	Job title:	Date:

Assessment type:

Initial assessment ☐	Re-assessment ☐	Other (please specify):	Date of next assessment:

Action Plan				
Ref	**Action required**	**By who**	**Target date**	**Completed (signed of)**

Action plan prepared by:		**Agreed by:**	
Signed:		**Date:**	
Action plan review dates:			

Appendix 1

Glossary of Abbreviations and Definitions

Authorised User
The authorised user is the individual who operates the laser/IPL equipment to treat patients/clients. He/she must sign a statement that they have read, understood and will comply with the Local Rules. They must be approved by the LPS and their name should appear on the List of Authorised Users. Only Authorised Users are permitted to fire the laser/IPL.

Core of Knowledge Core of Knowledge' refers to the minimum competency level in Class 3R, 3B and 4 laser and IPL safety to be achieved by staff that work with lasers/IPL equipment, It is considered good practice for staff to re-attend a Core of Knowledge course every five years in order to maintain their safety awareness levels. The Core of Knowledge syllabus is available at 10 | P a g e www.bmla.co.uk. A Safety Awareness Course (also available at www.bmla.co.uk) is recommended for those who are present during laser/IPL use but do not fire the laser themselves.

ERHP – Expert Registered Healthcare Professional
The ERHP is an expert doctor, dentist, clinical scientist or registered nurse with verifiable clinical expertise in using laser/IPLs to treat patients/clients and who can demonstrate that they have the necessary knowledge and experience to produce a protocol. The ERHP must also be registered with their appropriate professional body and must ensure that any protocols written are within their area of expertise.

IPL – Intense Pulsed Light
IPLs are powerful devices which are capable of emitting intense broadband, non-coherent, non-ionising electromagnetic radiation, which may or may not be precisely filtered and/or pulsed and whose purpose is to deliver energy over a specific range of wavelengths, to biological tissues, with the aim of causing a therapeutic effect to a person. For the purposes of these essential standards, IPLs are restricted to those sources intended to be used on people, excluding solaria, and ultraviolet radiation phototherapy and similar sources used under the supervision or direction of a registered medical practitioner.

Local Rules
The Local Rules refer to a document approved by the LPA describing the safe use of laser/IPL equipment, reflecting safe working practices and day-to-day safety management. The Local Rules are often produced by the LPA.

LPA – Laser Protection Advisor
The LPA is the person providing expert advice on laser/IPL safety. The LPA will be knowledgeable and have expertise in matters relating to the evaluation of laser and IPL hazards and have responsibility for advising on their control. The duties of the LPA include undertaking hazard analysis and risk assessment for each laser and IPL installation which are accepted by the employer to form part of the service's overall risk assessment framework. The LPA advises on laser/IPL safety training, the suitability of personal protective eyewear and ensuring that Local Rules are produced, signed, dated and implemented for each installation. The LPA may be an external adviser to the laser/IPL healthcare establishment and not necessarily be an employee.

LPS – Laser Protection Supervisor
The LPS is an individual within a laser/IPL healthcare establishment who is responsible for ensuring that all laser/IPL authorised users comply with the Local Rules, ensuring that all authorised users are appropriately trained to operate each laser/IPL and that the Local Rules document is followed on a day-to-day basis. In the event of an incident or near-miss, the LPS should inform the LPA. There must be easy communication between LPS and LPA. The LPS is usually an employee of the laser/IPL establishment.

MHRA – Medicines and Healthcare products Regulatory Agency
The MHRA is an executive agency of the Department of Health whose principal aim is to safeguard the public's health in the use of medicines and medical devices. 11 | P a g e