

Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications



MAY 2017

Contents

| | Page |
|--|------|
| Foreword | 3 |
| Standard 1: Patients / clients will receive treatment using Class 3B and Class 4 lasers and IPLs in accordance with safe and appropriate procedures. | 4 |
| Standard 2: Patients / clients will receive treatment from appropriately trained and competent laser / IPL operators | 6 |
| Standard 3: The treatment environment in which Class 3B and Class 4 lasers and IPLs are used is safe | 8 |
| Appendix 1: Glossary of abbreviations and definitions | 9 |
| Appendix 2: Registration schemes | 12 |
| Appendix 3: Bibliography | 13 |
| Appendix 4: Acknowledgements | 14 |

Foreword

These standards are specifically for non-surgical aesthetic applications of Class 3B¹ and Class 4 lasers and Intense Light Sources, commonly called Intense Pulsed Lights (IPLs).

These standards have not been produced to take account of Low Level Laser Therapy (LLLT) provided by healthcare professionals using a Class 3B laser. However the best practice principles of the standards may be adopted by practitioners providing LLLT.

The Care Quality Commission (CQC) registration system of the Health and Social Care Act 2008 (HSCA) came into force on 1 October 2010 for independent healthcare providers in England. In this system providers are required to register with CQC if they provide a regulated activity. The non-surgical use of lasers and IPLs is not subject to CQC regulation as it is not defined as a regulated activity. To determine which services are required to register with the CQC, the service provider should refer to the CQC web site guidance and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. From April 2016 regulation of specified groups of providers was introduced in Scotland with regulation provided by Healthcare Improvement Scotland. The providers identified in the legislation are doctors, dentists, nurses, midwives and dental care professionals.

Where a service provider is not required to register with the CQC when providing services using Class 3B, Class 4 and IPLs they should consider applying to a registration scheme (Appendix 2) to register their service, having demonstrated compliance to these standards and be included in the public register of validated providers.

These standards encompass aspects of the service-specific Laser and IPL standards that were first introduced in 2002 by the Department of Health (*National Minimum Standards for Independent Healthcare*). They reflect essential arrangements for safety and quality in the provision of the non-surgical use of the lasers and IPLs and will be kept under review. These standards are for operators and providers of services and it is envisaged that regulators such as Local Authority Environmental Health Inspectors will use the standards in their assessments of compliance for Class 3B, Class 4 lasers and IPLs.

These standards have been published by the British Medical Laser Association (BMLA) and are based on standards developed by Treatments You Can Trust (TYCT), Association of Laser Protection and Healthcare Advisers (ALPHA) and the Hairdressing and Beauty Industry Authority (HABIA).

Finally, it should be emphasised that responsibility for the provision of good quality, safe treatment lies with the service provider.

¹ This does not include Class 3B lasers operated by a healthcare professional previously afforded exemption under the Care Standards Act 2000 for non-aesthetic applications as explained further in Appendix 1.

Standard 1

Standard 1: Patients/clients will receive treatment using Class 3B and Class 4 lasers and IPLs in accordance with safe and appropriate procedures.

1.1 A treatment protocol², produced by an Expert Registered Healthcare Professional (ERHP) in relation to the practitioner's relevant area of practice is followed which sets out the necessary pre-treatment checks and tests, the manner in which the procedure is to be applied, the acceptable variations in the settings used, and when to abort a treatment. The treatment protocol must be traceable, the ERHP to confirm authorisation and validity, and it should be reviewed either when there is a change of treatments or if evidence comes to light that shows a change is in the clients' interests. A separate treatment protocol must be in place for each laser or IPL treatment. In particular, the protocol must address:

- contraindications;
- technique;
- obtaining patient/client consent prior to treatment;
- record keeping requirements and treatment process (step by step guidance);
- cleanliness and infection control within the treatment environment;
- pre-treatment tests;
- post-treatment care;
- recognition of treatment-related problems;
- procedure if anything goes wrong;
- permitted variation on machine variables.

The arrangements must provide evidence of the means by which the ERHP provides ongoing support and advice.

1.2 Operators must ensure patient/client safety by:

- checking with patients/clients if they have (or have had) any medical condition or are having (or have had) any treatment for which laser or intense light treatment would be a contraindication;
- where appropriate, covering the skin outside the area being treated;
- where appropriate, checking the skin type and pigmentation prior to treatment.

1.3 Local Rules produced under the advice and approval of a certificated Laser Protection Advisor (LPA) for the use of laser and IPL devices, including when they are being used on a trial or demonstration basis, and these cover:

- the potential hazards associated with lasers and/or IPLs;
- controlled and safe access;
- authorised user's responsibilities;
- methods of safe working;
- safety checks;
- normal operating procedures;
- personal protective equipment, where appropriate;
- prevention of use by unauthorised persons;
- adverse incident procedures;
- procedure in the event of equipment failure.

² The ERHP treatment protocol is an overarching protocol per procedure the service offers but it is not patient / client specific.

- 1.4 Laser and IPL users have access to safety advice from a certificated laser protection adviser (LPA). Evidence of the LPA's laser/IPL certification³ should be available for reference on site.
- 1.5 Evidence should be available to show that the LPA has carried out an initial site visit and produced a laser/IPL risk assessment of the establishment. The risk assessment should be signed, dated and include a date for next review/assessment. The employer accepts the laser/IPL risk assessment and incorporates this into the service's overall risk assessment framework. A laser/IPL safety audit should be completed every year, and an on-site visit every four years by the LPA.
- 1.6 The Local Rules document must be in place on-site, issued, signed and dated by both the employer and by the LPA. Local Rules should be reviewed annually including a projected date for review.
- 1.7 A register must be maintained of the named person/s authorised to operate lasers and IPLs. Authorised users must sign to indicate that they accept, understand and agree to work to the Local Rules.
- 1.8 A person with overall on-site responsibility for lasers and intense lights is appointed (Laser/IPL Protection Supervisor - LPS). The LPS must attend a laser/IPL Core of Knowledge safety course. This training must include the relevant safety management aspects that allow them to perform their role effectively and be repeated periodically at least every 5 years. The LPS must maintain evidence of Continuing Professional Development (CPD) to demonstrate knowledge and skills relevant to the treatments carried out. CPD reflects training needs in response to changes in equipment, practice and the treatment environment.
- 1.9 A treatment register must be maintained every time the laser or IPL is operated, including:
 - the name of the person treated (including a second means of identification, such as a date of birth);
 - the date and time of treatment;
 - the name and signature of the laser/IPL operator;
 - the nature of the laser/IPL treatment given;
 - the treatment parameters; and
 - any accidents or adverse effects.
- 1.10 Arrangements must be in place to ensure valid written consent is gained from the patient/client by the laser/IPL operator including an explanation of risks, benefits and complications of treatment. Additional arrangements are in place for seeking consent from persons under 18 years of age from appropriately trained laser/IPL operators. Arrangements should follow Department of Health guidance.
- 1.11 The laser/IPL operator is responsible for the quality and safety of the procedure carried out. Adherence to these standards will facilitate this but does not remove the responsibility from the operator.

³ The registration scheme would need to be assured of the quality of the LPA being used

Standard 2

Standard 2: Patients/clients will receive treatment from appropriately trained and competent laser/IPL operators.

- 2.1 All laser and IPL system users must demonstrate evidence of having attended laser/IPL operator training (evidence should include the training curriculum), which is system specific and treatment specific. Evidence of training attendance certificates should be held within the establishment.
- 2.2 All laser/IPL treatment operators must attend a laser/IPL Core of Knowledge safety training course of a minimum of three hours duration as described in the joint BMLA/IPEM/SRP approved Core of Knowledge syllabus or the MHRA September 2015 Guidance. Core of Knowledge training must be repeated periodically at least every 5 years. Evidence of training attendance certificates, including who provided the training and its contents, should be held within the establishment.
- 2.3 All staff using lasers and IPLs must maintain evidence of Continuous Professional Development (CPD) to demonstrate knowledge and skills relevant to the treatments carried out. CPD must reflect training needs in response to changes in equipment and technology, practice and the treatment environment. Update training may include private study, attendance at meetings, exhibitions, learning and training events, etc. A written record should be kept to demonstrate evidence of attendance and programme of study.
- 2.4 All operators of lasers and IPLs must use them only for treatments for which they have been trained and are competent. Evidence of training records must be held within the establishment for confirmation.
- 2.5 Compliance with the Qualification Requirements published by Health Education England, 2015, (Developing People for Health and Healthcare, Part One: Qualification Requirements for Delivery of Cosmetic Procedures: Non-surgical Cosmetic Interventions and Hair Restoration, November 2015, NHS Health Education England) would be accepted as fulfilling the necessary training requirements. These requirements apply to all practitioners, regardless of previous training and professional background, ranging from doctors and dentists and other regulated health professionals to those with beauty therapy background. Following the terminology adopted by the Higher Education Institutions (HEI),
 - Successful completion of training at Level 4 enables practitioners to use lasers and IPL for hair removal/reduction (excluding treatments within periorbital rim); use non-ablative lasers, IPL and LED for photo rejuvenation including sun-induced benign dyschromia (excluding treatments within periorbital rim); use LED for clinically diagnosed acne vulgaris.
 - Successful completion of training at Level 5 enables practitioners to use laser treatments for tattoo removal (excluding treatments within periorbital rim); use lasers and IPL treatments for benign vascular lesions (excluding treatments within periorbital rim)
 - Successful completion of training at Level 6 enables practitioners to deliver ablative fractional laser treatments (excluding treatments within periorbital rim); use laser and IPL treatments for generalised and discrete pigmented lesions (excluding treatments within periorbital rim);
 - Successful completion of training at Level 7 enables practitioners to deliver laser treatments of any sort within the periorbital rim (excluding treatments on or within the eyeball) subject to oversight of registered clinical professionals

(doctors, dentists, nurses, clinical scientists); deliver fully ablative skin treatments (ie non-fractional resurfacing) limited to GMC-registered practitioners with a licence to practise only;

Assessment of proficiency in delivery of procedures is required prior to attaining each recognised level. The principle of Accreditation of Prior Learning is accepted and this takes into account current knowledge from formal study and qualifications or through practical experienced gained in the clinic.

Standard 3

Standard 3: The treatment environment in which Class 3B and Class 4 lasers and IPLs are used is safe.

- 3.1 The area around working lasers and IPLs must be controlled to protect other persons while treatment is in progress. The Controlled Area must be clearly defined and not used for other purposes, or as access to other areas, when laser/IPL treatment is being carried out.
- 3.2 While the equipment is being operated, the authorised user is responsible for the safety of all persons in the Controlled Area. No other laser or IPL should be in the 'Ready' state in the same Controlled Area at the same time.
- 3.3 All lasers and IPLs must comply with current standards (e.g. BS EN 60601-2-22:2013 for medical lasers and BS EN 60601-2-57:2011 for IPL) including, but not limited to having labels in accordance with standards, identifying them, their wavelength or range of wavelengths and the maximum pulse fluence/energy/power of the radiation emitted. These must be in a clearly visible space on the front or sides of the machine.
- 3.4 In establishments with Class 3B lasers, Class 4 lasers and IPL, suitable area warning signs must be displayed on the outside of doors to the controlled area.
- 3.5 Effective protective eyewear must be worn by everyone within the Controlled Area whenever there is a risk of exposure to hazardous levels of laser radiation or IPL light, as advised by the LPA. All protective eyewear must be marked with the wavelength range and protection offered in accordance with LPA advice taking account of BS EN 207:2009 for lasers and BS ISO 12609-1 and -2:2013 for IPLs. The specification of the required protective eyewear must be indicated in the Local Rules document and the specification of the eyewear in use must be at least to this level.
- 3.6 For all laser and IPL sources with a key switch, formal arrangements must exist for the safe custody of the key, separate from the equipment. Only authorised users have access to the key. Equivalent arrangements exist for equipment protected by passwords instead of a key switch.
- 3.7 The operating key must not be left unattended with the laser/IPL equipment. The Local Rules document must set out the procedures to be followed to ensure that unauthorised persons do not operate the laser or IPL when the machine is left unattended by an authorised user.
- 3.8 Lasers and IPLs must be serviced and maintained according to the manufacturer's instructions to ensure they are operating within their design specification. The user must ensure that the service agent services the laser/IPL in accordance with the manufacturer's specification. A record of servicing and repairs is kept.
- 3.9 Lasers and IPLs must have an electrical safety test carried out annually.

Appendix 1

Glossary of Abbreviations and Definitions

Aesthetic/Cosmetic

The words 'aesthetic' and 'cosmetic' can be used interchangeably to refer to treatments which are intended to resort or improve a person's appearance.

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.

Class 3B Lasers

Class 3B lasers are commonly used for physiotherapy treatments for pain relief in neck, back, neuralgia, tendinopathy and osteoarthritis conditions, post-operative pain relief and tissue healing as well as in laser research. Radiation in this laser class can be a hazard to the eye and, under some circumstances, the skin. A Class 3B laser produces intense optical radiation such that the maximum permissible exposure for eye exposure may be exceeded and direct viewing and specular reflections are potentially dangerous. However, viewing of the diffuse reflection (i.e., that which is scattered from a diffusing surface) is generally safe. For a continuous wave laser the maximum output of the laser at wavelengths above 315 nm must not exceed 500 mW.

Class 4 Lasers

Class 4 laser equipment is used in a variety of healthcare establishments. In non-surgical healthcare settings, Class 4 lasers are used to provide minimally or non-invasive cosmetic treatments such as removal of hair, tattoos, birthmarks or other blemishes from the skin. Class 4 laser equipment is powerful and if used incorrectly or becomes faulty, has the potential to cause serious injury to patients/clients receiving treatments, persons operating them, other persons in the vicinity or to ignite flammable materials.

Competence

Competence describes professional capability or ability to perform a task to the required standard. Service providers can demonstrate competence by obtaining qualifications that are issued by a recognised educational body and mapped to the Qualifications and Credit Framework (QCF) and the Scottish Credit and Qualifications Framework (SCQF). Guidance on qualification and oversight/supervision by non-surgical procedure as well as entry requirements is given in Health Education England (HEE) 'Part one: Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery' (November 2015). HEE prefers the term 'proficiency' which requires a practitioner to see systems holistically, receive deviations from the normal pattern and have a higher level of decision-making.

Compliance

Service providers can demonstrate compliance through regular independent audit by a competent person such as a certificated LPA and through the risk assessment process. Compliance with these standards is ultimately regulated by Local Authority Environmental Health Inspectors and enforced under the provisions of the Health and Safety at Work Act 1974 and other applicable UK regulation.

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

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 solarium, 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.

LLLT - Low Level Laser Therapy

LLLT mainly uses a Class 3B laser. Core generic applications of LLLT are in wound healing and soft tissue repair; pain relief and non-needle stimulation of acupuncture and trigger points. Its range of application is wide and therefore so is the range of practitioners that use them. Where Class 3B lasers are used by registered healthcare professionals to provide LLLT such users are exempt from the requirements in this document but may be required to be registered with the CQC if falling within a regulated activity. Although the risk of serious skin injury during such treatments is relatively low, it must however be noted that Class 3B lasers can present a serious eye hazard, and the principles of these standards are recommended to practitioners providing LLLT.

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.

Non-surgical treatments or applications

The treatments covered by these standards include:

- Fully ablative skin treatments (complete removal of tissue to a depth beyond the epidermis and across an extensive area of skin)
- Laser treatment within the orbital rim (eyelid or in the immediate vicinity of the eye) but not on the eyeball
- Ablative fractional laser treatments (complete removal of tissue to a depth beyond the epidermis with this effect limited to small and discrete damage zones)
- Treatment of discrete pigmented lesions (Café au lait, Naevus of Ota, Becker's Naevus)
- Treatments for tattoo removal
- Treatments for benign vascular lesions (cherry angioma, spider naevus, rosacea, actinic lentigo, port wine stain)
- Treatments for benign dyschromias (sun damage, benign lentigo, broken veins and capillaries)
- Hair removal
- Photorejuvenation (removal of wrinkles, spots and textures)
- LED/LLLT (acne, pain relief, wound healing)

Please note, this is not an exclusive list.

Appendix 2

Registration Schemes

LPA Registration

The Laser Protection Advisor (LPA) should be knowledgeable and have expertise in matters relating to the evaluation of laser and IPL hazards and have responsibility for advising on their control.

- A list of organisations which run LPA certification schemes is available in Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices MHRA 2015
- The RPA2000 LPA Certification Scheme can be found at <http://www.rpa2000.org.uk/lpa-certification-scheme/>
- Public Health England operate a certification scheme for their own staff

Clinic Registration

A Treatments You Can Trust register of compliant providers will be launched shortly



ERHP Registration

These are in preparation by, for example, British Medical Laser Association

Appendix 3

Bibliography

Consent to Treatment Guidance – Department of Health

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

Control of Artificial Optical Radiation at Work Regulations, 2010

http://www.legislation.gov.uk/ukxi/2010/1140/pdfs/ukxi_20101140_en.pdf

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications. Specification for products, BS ISO 12609-1:2013

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications. Guidance for use, BS ISO 12609-2:2013

Guidance for doctors who offer cosmetic interventions. General Medical Council, June 2016

Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices. MHRA 2015

Habia Laser and Light Standards, 2015

<http://nos.ukces.org.uk/Pages/results.aspx?u=http%3A%2F%2Fnos%2Eukces%2Eorg%2Euk&k=Habia%20laser%20and%20light>

Medical Electrical Equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment, 1996, BS EN 60601-2-22

Medical Electrical Equipment. Particular Requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use, 2011 BS EN 60601-2-57

Photobiological safety of lamps and lamp systems. Guidance on manufacturing requirements relating to non-laser optical radiation safety, 2008 BS EN 62471

Personal eye-protection. Filters and eye-protectors against laser radiation (laser eye-protectors), 2009, BS EN 207

Personal eye-protection. Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors), 2009, BS EN 208

Safety of laser products. Equipment classification and requirements, 2014, BS EN 60825-1

Appendix 4

Acknowledgements

| | |
|--------------------|---|
| Stan Batchelor | Guy's and St Thomas' NHS Foundation Trust |
| Dr Phil Dobson | Laser Care Services |
| Dr Jon Exley | Lynton Lasers & British Medical Laser Association |
| Prof Harry Moseley | British Medical Laser Association |
| Dr John O'Hagan | Public Health England |
| Mike Regan | Association of Laser Safety Professionals |
| Paul Stapleton | Mapperley Park Clinic |
| Sally Taber | Cosmetic Quality-Assurance Ltd |
| Tiffany Tarrant | Habia/Skills Active |
| Dr Godfrey Town | Association of Laser Protection and Healthcare Advisors |
| Paul Tozer | Lasermet |
| Andrew Wilby | Independent Healthcare Advisory Services (no longer exists) |