Essential Standards for Class 3B and Class 4 Lasers and Intense Light Systems (ILS) in non surgical applications

INDEPENDENT HEALTHCARE ADVISORY SERVICES

Association of Laser Protection Healthcare Advisers

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Contents

Foreword

It has been recognised previously that class 3B and class 4 lasers and Intense Light Systems should be regulated as they are powerful devices that need to be managed and used correctly. These standards are specifically for non-surgical applications such as those used in the cosmetic and beauty industry where it is not required to be medically qualified or a healthcare professional to provide such treatments. However these standards apply whether the operator is a healthcare professional or not when they are providing class 3B[1], class 4 and intense light systems in non-surgical applications.

These standards have not been produced to take account of the Low Level Laser Therapy (LLLT) provided by healthcare professionals using a class 3B laser. The provision of LLLT is exempted from these standards however the best practice principles of the standards may be adopted by practitioners proving LLLT.

The Care Quality Commission (CQC) registration system of the Health and Social Care Act 2008 came into force on 1 October 2010 for independent healthcare providers. In this system the non surgical use of lasers and Intense Light Systems is not regulated as it is not defined as a regulated activity according to the Registration Regulations. 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.

Where a service provider is not required to register with the CQC when providing services using class 3B, class 4 and Intense Light Systems they should seek to apply to the registration scheme[2] to register their service, having demonstrated compliance to these standards and be included in the public register of accredited providers.

IHAS and ALPHA have been seeking an alternative arrangement for the regulation of the non surgical use of class 3B and Class 4 lasers and Intense Light Systems to ensure there is a continued protection for the public, those using the equipment and a framework for providers to demonstrate they meet essential standards.

These standards have been developed using expertise and knowledge from within the industry and 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 intense light systems and will be reviewed after their first year of implementation. 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 intense lights.

[1] This does not include Class 3B lasers operated by a healthcare professional previously afforded exemption under the Care Standards Act 2000 and explained further in Appendix 1

[2] This registration scheme is being developed by IHAS and is expected to be available later in 2011

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CLASS 3B AND 4 LASERS AND/OR INTENSE LIGHT SYSTEMS

Proposed standards which should be in place in establishments using non surgical Class 3B and Class 4 Laser and Intense Light Systems (ILS) equipment to treat patients/clients

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Standard 1

Outcome – Patients/clients receive treatment using Class 3B and Class 4 lasers and intense light systems (ILS) in accordance with safe and appropriate procedures.

1.1
A treatment protocol[3], produced by an expert medical practitioner (EMP) or expert dental practitioner (EDP) 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 signed and dated by the EMP/EDP to confirm authorisation, should be reviewed annually and include a projected date for review. A separate treatment protocol must be in place for each laser or ILS treatment. In particular, the protocol must address:

- contraindications;
- technique;
- obtaining patient/client consent prior to treatment;
- 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;
- procedure in the event of equipment failure.

[3] The EMP treatment protocol is an overarching protocol per procedure the service offers but it is not patient/client specific

The arrangements must be evidenced, by which the EMP or EDP provide ongoing support and advice to respond to queries, incidents and emergencies raised by the operator requiring a medical or dental opinion in relation to the protocol.

1.2
The treatment protocol is supported by written procedures (the Employer is responsible for ensuring there are Local Rules produced under the advice and approval of a Laser Protection Advisor) for the use of laser and ILS devices, including when they are being used on a trial or demonstration basis, and these cover:

- the potential hazards associated with lasers and/or intense lights;
- 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; and
- adverse incident procedures.

1.3
Operators must ensure patient/client safety by:

- checking with patients/clients if they have any medical condition or 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.

1.4
Laser and intense light users have access to safety advice from a certificated laser protection adviser (LPA). Evidence of the LPA's laser/ILS certification[4] and experience should be available for reference on site.

[4] The regulator/assessor would need to be assured of the quality of the LPA being used

1.5
There is evidence that the LPA has carried out an annual site visit including a laser/ILS 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/ILS risk assessment and incorporates this into the service's overall risk assessment framework.

1.6
The Local Rules document must be in place on site, issued, signed and dated by both the employer and by a Laser Protection Advisor (LPA). Local Rules should be reviewed annually including a projected date for review.

1.7
The Local Rules document (covering point 1.2 above) must highlight the named person/s authorised to operate lasers and intense lights. Authorised users must sign to indicate that they accept, understand and agree to work to the Local Rules procedures drawn up for the use of lasers and intense lights in the establishment.

1.8
A person with overall on-site responsibility for lasers and intense lights is appointed (Laser/ILS Protection Supervisor - LPS). The LPS must attend a laser/ILS 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 as a minimum every 3 to 5 years. The LPS must maintain evidence of Continued 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 ILS 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/ILS operator;
- the nature of the laser/ILS treatment given
- the treatment parameters and
- any accidents or adverse effects.

1.10
Arrangements are in place to ensure valid written consent is gained from the patient/client by the laser/ILS 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/ILS operators. Arrangements should follow Department of Health guidance.

Standard 2

Outcome – Patients/clients will receive treatment from appropriately trained and competent laser/ILS operators.

2.1
All laser and intense light system users must demonstrate evidence of having attended laser/ILS 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/ILS treatment operators must attend a laser/ILS Core of Knowledge safety training course of a minimum of three hours duration as described in MHRA DB 2008(03) *"Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices"* Core of Knowledge training must be repeated a minimum of between 3 and 5 years. Evidence of training attendance certificates should be held within the establishment.

2.3
All staff using lasers and intense light systems in addition to the Core of Knowledge training must maintain evidence of Continued 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 intense light systems 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.

Standard 3

Outcome - The treatment environment in which Class 3B and Class 4 lasers and intense light systems (ILS) are used is safe.

3.1
The area around working lasers and intense light systems 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/ILS 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 intense light system should be in use (i.e. in the 'Ready' state) in the same controlled area at the same time.

3.3
All lasers and intense light systems must comply with current standards (BS EN 60601-2-22 for medical lasers and BS 60601-2-57 [Draft] for ILS) including, but not limited to having labels in accordance with standards, identifying them, their wavelength or range of wavelengths and the maximum output 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 ILS, 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 or intense light radiation. All protective eyewear must be marked with the wavelength range and protection offered. The specification of the required protective eyewear must be indicated in the Local Rules document and match the specification of the eyewear in use.

3.7
For all laser and intense light sources with a key switch, formal arrangements 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.

3.8
The operating key must not be left unattended with the laser/ILS equipment. The Local Rules document must set out the procedures to be followed to ensure that unauthorised persons do not operate the laser or ILS when the machine is left unattended by an authorised user.

3.9
Lasers and intense light systems 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 / ILS in accordance with the manufacturer's specification. A record of servicing and repairs is kept.

3.10
Lasers and intense light systems must have an electrical safety test carried out annually.

Appendix 1 – Glossary of Abbreviations and Definitions

Abbreviations and Definitions

Authorised User
The authorised user is the individual who operates the laser/ILS equipment to treat patients/clients.

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 light 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.

Intense Light Systems (ILS)
Intense light systems 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. ILS also encompasses intense pulsed light (IPL) sources. For the purposes of these essential standards, intense light systems are restricted to those sources intended to be used on people, excluding specific equipment, such as public solaria and ultraviolet radiation phototherapy and similar sources used under the supervision or direction of a registered medical practitioner.

EMP – Expert Medical Practitioner
The EMP is a qualified medical practitioner with verifiable clinical expertise in using laser/intense light systems to treat patients/clients.

EDP – Expert Dental Practitioner
The EDP is a qualified dental practitioner with verifiable clinical expertise in using laser/intense light systems to treat patients/clients.

Local Rules
The local rules are contained within a document produced by the Laser Protection Advisor describing the procedures to use laser/ILS equipment, reflecting safe working practices and day-to-day safety management.

Low Level Laser Therapy (LLLT)
LLLT mainly uses a Class 3B laser. Core generic applications of LLLT are optimised 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. This exemption is intended to be an equivalent exemption as afforded by the Private and Voluntary Healthcare (England) Regulations 2001. "Health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies: The professions referred to are—

(a) the professions regulated by the Pharmacy Act 1954, the Medical Act 1983, the Dentists Act 1984, the Opticians Act 1989, the Osteopaths Act 1993 and the Chiropractors Act 1994,
(b) the professions regulated by **[**the Nursing and Midwifery Order 2001**]** ,
(c) the professions regulated by **[**the Health Professions Order 2001**]** ,
(d) any other profession regulated by an Order in Council under this section.

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/ILS safety. The LPA will be knowledgeable and have expertise in matters relating to the evaluation of laser and intense light system (ILS) 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 ILS system installation which are accepted by the employer to form part of the service's overall risk assessment framework. The LPA advises on laser/ILS 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/ILS healthcare establishment and not necessarily be an employee.

LPS – Laser Protection Supervisor
The LPS is an individual within a laser/ILS healthcare establishment who is responsible for supervising the work of all laser/ILS authorised users, the safety and security of all laser/ILS, ensuring that all authorised users are appropriately trained to operate each laser/ILS and that the local rules document is followed on a day to day basis. The LPS is usually an employee of the laser/ILS 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.

Appendix 2 – Laser Protection Advisor Qualifications

Laser Protection Advisor Qualifications

The Laser Protection Advisor (LPA) should be knowledgeable and have expertise in matters relating to the evaluation of laser and intense light system (ILS) hazards and have responsibility for advising on their control. The following organisations run LPA certification schemes.

A list of organisations which run LPA certification schemes is available in MHRA Bulletin DB2008(03) clause 3.3.2.

http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON014775

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- **Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic *practices***
  MHRA DB 2008(03)
http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON014775

- **Consent to Treatment Guidance – Department of health**
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

British Standards

- **Safety of laser products. Equipment classification and requirements, 2007**
  BS EN 60825-1

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

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

- **Personal eye-protection. Filters and eye-protectors against laser radiation (laser eye-protectors), 1999**
  BS EN 207

- **Personal eye-protection. Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors), 2010**
  BS EN 208

- **Eyewear for protections against intense light sources used on humans and animals for cosmetic and medical applications – Part 1: Specification for products**
  BS 8497-1

- **Eyewear for protection against intense light sources**
  BS 8497-2

- **Control of Artificial Optical Radiation at Work Regulations, 2010**
  http://www.legislation.gov.uk/uksi/2010/1140/pdfs/uksi_20101140_en.pdf

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