Independent Clinics
Lasers and Intense Pulse Light Source Treatments

Registration & Inspection Unit

May 2016

Review date June 2019

Department of Health and Social Care
Rhyenn Slaynt as Kiarail y Theay
Prescribed Techniques and Prescribed Technology

Establishments in which treatments are provided using certain techniques and technology are regulated under the Regulation of Care Act 2013. These are techniques or technology – such as lasers – that require expertise in delivery, the use of appropriate equipment and for the setting to have certain measures in place in order for the treatment to be delivered safely.

The Registration and Inspection Unit will maintain regulation of the techniques and technology currently regulated (other than by or under the supervision of registered health care professionals) and future regulation will be extended to include treatment using intense pulsed light sources and to hyperbaric oxygen treatment/therapy. The reasoning for this is set out below.

Class 3B and 4 Lasers and/or Intense Pulsed Light Sources

The standards cover both Class 3B and 4 lasers and intense pulsed lights, as these technologies share similar features. Intense pulsed lights are defined, in regulation 3 of the Private and Voluntary Health care Regulations, as:

Broadband non-coherent light which is filtered to produce a specified range of wavelengths; such filtered radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues.

Class 3B lasers are concentrated energy sources used for physiotherapy, eg to relieve chronic pain and backache by ‘massaging’ the tissue by pulsing the beam through it; for acupuncture; and for wound healing, for instance pressure sores, venous and diabetic ulcers, and for softening scar tissue. The majority of users are State Registered and/or Chartered Physiotherapists and Podiatrists – who will be exempted from regulation (see above).

Class 4 lasers and pulsed light sources are used in a variety of settings and for a variety of purposes. For instance, they are used for medical treatment in acute hospitals; in dental treatment; and in establishments ranging from clinics providing invasive cosmetic surgery by medical practitioners, to beauty salons where operators provide minimally or non-invasive cosmetic services which do not require the operator to be medically qualified. These include the removal of hair, tattoos, birthmarks or other blemishes from the skin. Class 4 lasers and intense pulsed lights are powerful devices which, if faulty or used incorrectly, have the potential to cause serious injury to those operating them, recipients of the treatment and other persons in the vicinity, and to ignite flammable materials.

It is essential, therefore, that all establishments that provide treatment using Class 3B lasers (except where the laser is used by or under the supervision of a health care professional), Class 4 lasers or intense pulsed light sources, whether for medical or cosmetic treatment, are effectively regulated by the Inspection Unit so that recipients of treatment and those who work or come within the confines of the regulated establishment are protected from laser and intense pulsed light emissions.

We regard that the key elements in ensuring that lasers and intense pulsed lights sources are used safely centre around:
clear lines of responsibility within the registered establishments on the use of lasers and intense pulsed lights, including a clear understanding by all users of the personal responsibility that using lasers and intense pulsed lights entails;

- clear policies and procedures on the use and maintenance of lasers and intense pulsed lights;

- users of laser and intense pulsed lights undergoing specialised training, and learning, maintaining and updating an effective core of knowledge about the use and impact of lasers and intense pulsed lights;

- effective record keeping;

- safe working areas; and

- protective eyewear and other risk-avoidance measures.

The attached standards reflect this.
Core standards

Most core standards will be applicable to you as a provider of a laser and intense pulsed light system. These are:

<table>
<thead>
<tr>
<th>Standard number and domain</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Information for service recipients</td>
<td>All applicable</td>
</tr>
<tr>
<td>2  Quality of treatment and care</td>
<td>The majority are applicable</td>
</tr>
<tr>
<td>3  Environmental, Personal Safety &amp; Comfort</td>
<td>The majority are applicable</td>
</tr>
<tr>
<td>4  Equipment &amp; Supplies</td>
<td>All applicable</td>
</tr>
<tr>
<td>5  Staffing</td>
<td>The majority are applicable if staff are employed</td>
</tr>
<tr>
<td>6  Management, Quality &amp; Improvement</td>
<td>All applicable</td>
</tr>
<tr>
<td>7  Practicing Privileges</td>
<td>All applicable if you are granting practicing privileges to healthcare professionals to provide laser or intense pulsed light system treatments</td>
</tr>
<tr>
<td>8  Risk Management</td>
<td>The majority are applicable</td>
</tr>
<tr>
<td>9  Medicines Management</td>
<td>Some may be applicable e.g. some clinics use local anaesthetic creams</td>
</tr>
<tr>
<td>10 Record Management</td>
<td>All applicable</td>
</tr>
<tr>
<td>11 Research</td>
<td>All applicable</td>
</tr>
</tbody>
</table>
Class 3B and 4 Lasers and/or Intense Pulsed Light Sources

Procedures for Use of Lasers and Intense Pulsed Lights

**OUTCOME**
Patients receive treatment using lasers and intense pulsed lights from competent operators and in accordance with appropriate procedures.

**STANDARD P1**

P1.1 A protocol produced by an expert medical or expert registered healthcare professional 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. In particular, the protocol addresses:

- 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 with treatment;
- permitted variation on machine variables;
- procedure in the event of equipment failure.

P1.2 The protocol is supported by written procedures for the use of devices, including when they are being used on a trial or demonstration basis. These procedures are produced in accordance with the advice and the approval of a recognised laser protection advisor and cover:

- the potential hazards for staff and clients associated with lasers and/or intense lights;
- controlled and safe access;
- authorised users’ responsibilities;
- methods of safe working;
- safety checks;
- normal operating procedures;
- personal protective equipment;
- prevention of use by unauthorised persons; and
adverse incident procedures.

P1.3 There is a register of persons authorised to use lasers and intense lights. Authorised users sign to indicate that they accept and understand the procedures drawn up for the use of lasers and intense lights in the registered establishment.

P1.4 Laser and intense light users have access to safety advice from a certificated laser protection adviser. Written agreements are in place which include details of who to contact for advice, emergency cover arrangements and the frequency of site visits.

P1.5 A person with overall on-site responsibility for lasers and intense lights is appointed.

P1.6 Records are maintained every time the laser or intense light is operated, including:
- the name and date of birth of the person treated;
- the date and time of the treatment;
- the name and signature of the operator;
- the nature of the treatment given and its parameters; and
- any accidents or adverse effects.

Training for Staff using Lasers and Intense Pulsed Lights

OUTCOME
Patients receive treatment from appropriately trained operators.

STANDARD P2

P2.1 All laser and intense pulsed light users have core knowledge training of a minimum of three hours duration; this training to be documented and to be in accordance with the guidance issued by the Medicines and Health Care Products Regulatory Agency (MHRA) “Lasers, intense light source systems and LED’s – Guidance for safe use in medical, surgical, dental and aesthetic practices.” September 2015. The training will include:
- characteristic features of light from lasers and intense pulsed light sources;
- hazards from device malfunction;
- equipment management;
- effects of light on the eye, skin and body tissues;
- safety management, including Local Rules and controlled areas;
- minimising risks;
action to be taken in the event of an adverse incident.

The core knowledge training to be repeated at 3 yearly intervals and evidence in the form of attendance certificates held on the operator’s staff file.

- P2.2 All staff using lasers and intense pulsed lights have regular update training, both planned and in reaction to relevant technological and medical developments.

- P2.3 All operators of lasers and intense pulsed light sources use them only for treatments for which they have been trained and, where appropriate, hold qualifications.
Safe Operation of Lasers and Intense Pulsed Lights

OUTCOME
Patients receive treatment using lasers and intense pulsed lights from competent operators and in accordance with appropriate procedures.

STANDARD P3

P3.1 The area around working lasers and intense pulsed light sources is 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.

P3.2 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 pulsed light source is in use in the same controlled area at the same time.

P3.3 All lasers and intense pulsed light sources will comply with current standards in place (e.g. BSEN 60601-2-22 for medical laser and BS 60601-2-57 for ILS) including, but not limited to having labels, in accordance with the standards, identifying the device, 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.

P3.4 In establishments with class 4 lasers, warning signs as specified in EN 60825-1 are displayed on the equipment and on the outside of doors to the controlled area.

P3.5 Protective eyewear is worn by everyone within the controlled area whenever there is a risk of exposure to hazardous levels of laser or intense pulsed light radiation. All protective eyewear to be marked with the wavelength range and protection offered. The specification of the eyewear to be indicated in the protocol and will match the specification of the eyewear use. All protective eyewear to be checked daily.

P3.6 Operators ensure patient safety by:

- checking with patients if they have any medical condition or treatment for which laser or intense pulsed light treatment would be a contraindication; including herbal remedies.
- where appropriate, covering the skin outside the area being treated;
- where appropriate, checking the skin type and pigmentation prior to treatment.

P3.7 For all lasers and intense pulsed 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. The key is not left unattended with the equipment. Arrangements for safe custody of the key are included in the written protocol.

P3.8 Lasers and intense pulsed light sources are regularly serviced and maintained to ensure they are operating within their design specification. A record of servicing and repairs is kept; this will include a calibration certificate.