Nottinghamshire County Council Act 1985 (Part IV)
Licensing of Premises for Massage or Special Treatments
December 2012

Licence conditions for the Use of Class 3B and Class 4 Lasers and Intense Light Systems

In these conditions:-

Authorised User	***Means any person who is suitably qualified to use Class 3B and Class 4 Lasers and/or Intense Light Systems at the Premises***
The Controlled Area	***Means the room in which a specified piece of the Prescribed Equipment is used***
Expert Medical Practitioner (EMP)	***Means a person who is registered with the General Medical Council who can demonstrate that they have the necessary qualifications, expertise and experience to undertake competently and safely the service they provide; and have arrangements in place for continuing medical education relevant to the provision, or approval of, existing treatment protocols in the cosmetic use of a Laser or Intense Light System***
Intense Light System (ILS)	***Means an intense light, being broadband non-coherent light which may or may not be filtered to produce a specified range of wavelengths; such radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage or physiological changes to structures such as the hair follicles, skin blemishes, or blood vessels while sparing surrounding tissues as far as is reasonably practicable***
Laser	***Means a class 3B or class 4 laser product, as defined in part 1 of the British Standard EN60825-1 (Safety of laser products - Equipment classification and requirements)***
Laser Protection Advisor (LPA)	***Means any person holding a current Certificate of Competence from a recognised assessing body to act as a Laser Protection Adviser or Radiation Protection Adviser***
Laser Protection Supervisor (LPS)	***Means a person having undergone the laser safety Core of Knowledge as defined by the Medicines and Healthcare Products Regulatory Agency and who is employed at the Premises to ensure that the Local Rules, risk assessments, operating practices, policies and procedures are implemented***
The Local Rules	***Means the Risk Assessments and Operating Practices prepared in accordance with condition 3 below***
The Premises	***Means the premises identified in the body of this licence as the place in which the Prescribed Equipment is operated***
The Prescribed Equipment	***Means the Laser/Intense Light System (s) identified in the body of this licence, as stipulated in the Premises licence***
Specified Treatments	***Means the treatments identified in the body of this licence which are permitted to be carried out in the Premises using the Prescribed Equipment***
The Treatment Protocol	***Means a protocol produced or approved by an Expert Medical Practitioner (EMP) which includes the matters specified in condition 2.2 below***

0. Scope

These Conditions detail specific requirements for Lasers and Intense Light Systems in addition to the standard conditions prescribed under Part IV of the Nottinghamshire County Council Act 1985 applicable to all premises required to hold a licence for massage and/or special treatments.

1. Use of Lasers/ Intense Light Systems

1.1. Only the Specified Treatments may be provided at the Premises and only the Prescribed Equipment may be used to provide those Treatments.
1.2. No person shall be permitted to use the Prescribed Equipment unless they are appropriately trained in accordance with 7.1, below.
1.3. This Licence must be displayed in a prominent position within the Premises where it can be easily viewed by clients.
1.4. Written confirmation must be provided by the client prior to treatment that the risks and complications associated with the treatment which they are about to receive have been explained to them and have been understood by them, and that they consent to the treatment.
1.5. No persons under the age of eighteen (18) years may receive Specified Treatment(s) unless for the purpose of medical treatment provided under the supervision or direction of a registered medical practitioner.

2. Treatment Protocol

2.1. A Treatment Protocol must be produced by an expert medical practitioner and submitted to the Council for each treatment, specific to the Prescribed Equipment used, before that treatment is carried out or the equipment is used. If any revisions or amendments are made to the Treatment Protocol during the term of the licence, a copy of the revised Protocol must be submitted to the Council as soon as is reasonably practicable and in any event within 7 working days of those revisions taking effect.
2.2. A Treatment Protocol must include the following:
  2.2.1. name and technical specifications of the equipment to which the Protocol relates
  2.2.2. contraindications to treatment
  2.2.3. treatment technique – general
  2.2.4. the treatment technique specific to application
  2.2.5. the risks and complications to be explained to the client prior to treatment
  2.2.6. cleanliness and infection control
  2.2.7. pre-treatment tests
  2.2.8. post-treatment care
  2.2.9. recognition of treatment-related problems
  2.2.10. emergency procedures
  2.2.11. permitted variation on machine variables
  2.2.12. procedure in the event of equipment failure
  2.2.13. a version number or date
2.3. The treatment protocol must be signed by the EMP to confirm that the document is fit for purpose.
2.4. The Treatment Protocol must be followed at all times this licence is in force and the equipment remains Prescribed Equipment.

3. Local Rules

3.1. Local Rules must be produced and submitted to the Council for the Prescribed Equipment to be used at the Premises before that equipment is used. If any revisions

or amendments are made to the Local Rules during the term of the licence, a copy of the revised Local Rules must be submitted to the Council as soon as is reasonably practicable and in any event within 7 working days of those revisions taking effect.

3.2. The Licence holder must employ the services of a certified LPA to assist in the production of the Local Rules. The LPA must sign to confirm that they approve the Local Rules.

3.3. The LPA must visit the Premises in person initially to produce and audit the Local Rules, risk assessments and operating practices.

3.4. The Prescribed Equipment must only be used in accordance with the Local Rules

3.5. The Local Rules must include information on the following:

- 3.5.1. An assessment of the risks associated with the use of the Prescribed Equipment
- 3.5.2. Device description (including output, serial numbers etc) for all Prescribed Equipment
- 3.5.3. Make reference to the Treatment Protocol required by condition 2, above.
- 3.5.4. Written procedures for safe use of the Prescribed Equipment (to include information on prevention of use by unauthorised persons; safe operation of device etc)
- 3.5.5. Adverse incident procedures including actions that must be taken in cases of emergency e.g. eye exposure and details of the local accident and emergency department
- 3.5.6. Emergency shutdown procedures (as set down in manufacturer's instruction manual or treatment protocol)
- 3.5.7. Details of the nominated LPA (including his or her name, business address and telephone number)
- 3.5.8. Details of nominated the LPS (including his or her name, business address and telephone number)
- 3.5.9. Training requirements for Authorised Users for the use of Prescribed Equipment
- 3.5.10. A detailed plan of the Controlled Area(s), showing each piece of the Prescribed Equipment to be used in the Area and details of access to the Equipment, together with a complete plan of the Premises
- 3.5.11. Responsibilities of Authorised Users
- 3.5.12. Details of Protective eyewear (including information relating to when eyewear be worn and the minimum specification of protection required)

3.6. The Local Rules must be updated if there are any changes made to any of the items detailed in condition 3.5 above. Each update must be approved by the LPA.

3.7. The Local Rules relevant to each specific piece of Prescribed Equipment must be kept in the Controlled Area relating to that piece of Equipment whilst it is being operated.

4. Register of Authorised Users

4.1. A Register of Authorised Users must be kept at the Premises which includes details of trained personnel and signed declarations by those individuals stating that they accept and understand the procedures drawn up for the use of Lasers/ILS in the registered establishment).

4.2. Copies of the certificates held by the Authorised Users must be kept with the Register of Authorised Users.

4.3. Authorised Users must sign statements to the effect that they have read and understood and will follow Local Rules at all times.

5. Register of Laser Use

5.1. A register must be maintained for each piece of Prescribed Equipment to record the following information each time that equipment is operated:

- 5.1.1. the full name, date of birth and address of the person treated
- 5.1.2. date of treatment

5.1.3. the Authorised User's signature
5.1.4. the treatment given, including the site and an indication of the size of area, type of treatment; equipment used and Laser/ILS parameters used
5.1.5. any accident or adverse effects

5.2. The Register must be kept in the Controlled Area to which it relates at all times

5.3. The Register must be in a bound hard copy format with sequentially numbered pages. The front page must contain details of name and serial number of the equipment. Previous Registers must be retained for a period of no less than 3 years of the date of the last entry.

6. Laser Protection Supervisor

6.1. A suitably qualified and authorised member of staff having day to day responsibility for the Premises, must be identified as the Laser Protection Supervisor (LPS), who must ensure that the Register is maintained and the Local Rules and licence conditions are adhered to.

7. Training

7.1. All Authorised Users must hold the Core of Knowledge Training Certificate together with suitable and sufficient training provided by the manufacturer or supplier for each specific piece of Prescribed Equipment that they operate.

7.2. Authorised Users must only use the Prescribed Equipment for treatments for which they have received the appropriate training.

7.3. All Authorised Users must receive regular update training, both planned and in reaction to relevant technological and medical developments, at an interval of no less than once in every three year period.

7.4. Details of all training must be recorded in the Register of Authorised Users required by condition 4.1 above.

8. Controlled Area

8.1. Each piece of Prescribed Equipment must only be used in a Controlled Area designated for its use in accordance with condition 3.5.10 above.

8.2. The Controlled Area must be clearly defined and not used for any other purposes, or as access or egress to other areas, when treatment is being carried out.

8.3. An approved warning sign or light entry system which complies with current British Standards must be in place on the door of the Controlled Area. This sign must only be on display when the Prescribed Equipment is in use.

8.4. The door to the Controlled Area must be fitted with a suitable locking device to control access which can be operated from the outside in an emergency.

8.5. Any windows in the Controlled Area must be fitted with opaque blinds approved by the LPA, unless otherwise agreed in writing by the Local Authority.

8.6. The Controlled Area must be kept clear of clutter.

8.7. Surfaces within the Controlled Area must be of a matt or eggshell finish wherever possible. Mirrors and/or other reflective surfaces must be covered or removed during treatment, and jewellery must not be worn by the Authorised User or client.

8.8. All Prescribed Equipment must comply with current standards (BS EN 60601-2-22; BS EN 60825 series Safety of Laser Products and BS EN 60601-2-57 for ILS) and must display labels identifying them, their wavelength or range of wavelengths and the maximum output fluence, energy or power of the radiation emitted. The labels must be clearly visible on the front or side of the machine.

8.9. Lasers/ILS must be serviced annually or in accordance with the Manufacturers' Instructions, by a competent person. A record of all such servicing, and any repairs to the Laser/ILS equipment must be kept on the premises and a note made in the Register of Laser Use.

8.10. The LPS must ensure that the key to any Prescribed Equipment is kept in a secure and separate area when not in use and that only Authorised Users have access to the key.
8.11. No more than one piece of Prescribed Equipment must be switched on in the Controlled Area during client treatment.
8.12. When the Prescribed Equipment is in the stand-by mode or in operation the number of persons in the room must be kept to a minimum.

9. Protective eyewear

9.1. Protective eyewear which has been approved in writing by the LPA must be worn by everyone within the Controlled Area whenever there is a risk of exposure to the laser beam/intense light radiation.
9.2. All protective eyewear must be marked with the wavelength range and protection offered as detailed in the Local Rules and must comply with any relevant British Standard.
9.3. Protective eyewear must be maintained in a clean serviceable condition. Suitable storage must be provided for protective eyewear, to prevent damage and unauthorised access to the equipment.

10. Compliance with relevant legislation

10.1. It is the responsibility of the licensee to ensure compliance with all legislation in place at any particular time which is relevant to the business, including (but not limited to) that relating to Environmental Health, Trading Standards, Licensing, Fire Safety and Insurance.

11. Inspection of Records

11.1. All records and documents to which these conditions refer must be kept on the Premises and shall be available for inspection by an Officer authorised by the Local Authority on request.