

CONSULTATION DOCUMENT

Safety and Clinical Governance for Users of Lasers and Intense Light Devices

Godfrey Town, Laser Protection Adviser, Haywards Heath, UK.

In late 2002 England, Wales & Northern Ireland introduced regulatory controls (The Care Standards Act 2000) over private sector users and establishments operating lasers and intense pulsed light devices. Regulatory controls were seen as necessary as the use of such devices in the private beauty sector far outstripped the medical use of lasers and intense light systems by the National Health Service or private healthcare. The Regulations covered all users, including non-healthcare professionals such as beauty therapists, technicians, spa operators and physiotherapists using these devices for purely elective cosmetic treatments.

In the legislation, no distinction was made in law about which class of person should operate such devices, although at the consultation stages, attempts had been made by some medical speciality groups to restrict the use of these devices to their members. These efforts to control revenue in the private sector by medical vested interests were ignored by the legislators. However, every user and establishment had to comply with the provisions of the Regulations.

The Regulations are embodied in a document produced by the UK Dept of Health called "National Minimum Standards" and cosmetic users of these devices are required to comply with the provisions of two sections, Core Standards and Service Specific Standards.

As lasers and intense light systems are recognised as potentially hazardous devices, UK legislation as applied to cosmetic users of lasers and intense light systems essentially covers three major elements of management:

Safety

Safety controls are based upon pre-existing established standards for the safe use of Class IV medical lasers used for medical and technical applications. Key source documents include the international IEC equipment standard EN 60601-2-57, guidance on safe use standard EN60825-16 and the publication from the Dept of Health Medical Devices Agency, "Guidance on the safe use of lasers in medical and dental practice" 1995.

The key components include:

- A site visit by a technically competent person (Laser Protection Adviser) to identify potential hazards (**Risk Assessment**), check that suitable procedures are in place to ensure safe and controlled access, prevent use by unauthorised persons, ensure use of suitable safety equipment, ensure methods of safe working and ensure that authorised users are aware of their responsibilities.
- All users of lasers and intense light devices have training and update training including "Core of Knowledge" training in characteristics and effects of light on the eye, skin and body tissues, equipment management, safety management ("**Local Rules**"), minimising risks and action to be taken in the event of an adverse incident.
- Users only perform treatments for which they have been trained.
- That equipment is serviced and maintained regularly.

Clinical Governance

Non-invasive, superficial cosmetic treatments such as hair removal and skin rejuvenation have been the routine practice of beauty therapists or their predecessors for centuries. In recent decades, new beauty technologies have included needle electrolysis, light therapy, microdermabrasion, hydro-massage, suction massage, oxygen therapy, low-level laser

therapy, etc. The use of lasers and intense light devices represents an extension to these routine technologies.

In view of the concerns about new technology such as laser or intense light being used by inexperienced healthcare professionals and beauty therapists, the UK legislation requires **all users** of lasers and intense light devices to follow a **Treatment Protocol** "produced by an expert medical or dental practitioner". This document sets out in particular: contraindications, pre-treatment tests, technique, post-treatment care, recognition of treatment-related problems, procedure if anything goes wrong and procedure in the event of equipment failure.

All other medical issues arising with a client are referred back to the responsible general medical practitioner.

NB. Since treatments are superficial and non-invasive, the beauty therapist is able to deal with normal treatment-related problems using non-prescription, over-the-counter products.

As a beauty specialist in skin care, the therapist is able to identify many skin conditions and if concerned about any particular condition observed, encourages the client to seek proper medical advice.

General Controls

Establishments using lasers and intense light devices are required by legislation to maintain the following documentation:

- A Statement of Purpose
- A Patients' (or Clients') Guide
- A Complaints Procedure
- A Treatment Register (date, name, DOB, treatment performed, operator)
- Detailed Client Records
- An Accident Record Book

In addition, establishments have to maintain a set of **Policies & Procedures** detailing: information for patients, quality of care monitoring, client satisfaction survey, employment, training, complaints management, maintenance of premises and equipment, risk management, health and safety.

Notes:

UK beauty therapists are trained to a minimum of NVQ Level 3 at private and government colleges across the country. Some therapists progressing to advanced courses in treatments such as electrolysis, laser or intense light use, have to achieve NVQ Level 4.

National Vocational Qualification or NVQ, is a certificate of vocational education in the United Kingdom awarded for competent performance in work-based activities. NVQ Level 3 certification confirms competence that involves the application of knowledge in a broad range of varied work activities performed in a wide variety of contexts, most of which are complex and non-routine. There is considerable responsibility and autonomy and control or guidance of others is often required.

Correspondence: Godfrey Town godfreytown@mac.com