

Registration Consultation  
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Quarry House  
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20 May 2009

**Response to consultation on the  
framework for the registration of  
health and adult social care providers  
and consultation on draft Regulations**

**Consultation Document (30 March 2009)**

***Comments from  
The Association of Laser Safety Professional (ALSP)***

***on***

***Sections 3.48 to 3.52  
Regulation of non-surgical lasers and intense pulsed light equipment***

The ALSP is a professional society of laser safety experts actively engaged in providing advice, support and training in laser and intense light safety. For further detail concerning ALSP please see: <http://www.laserprotectionadviser.com/>

The ALSP responded to last year's consultation: Private and Voluntary Health Care - Care Standards Act 2000 - Regulations and National Minimum Standards Consultation Document (18 March 2008). Our response was detailed in my letter to Minister Ben Bradshaw (14 May 2008). In particular we expressed our concerns in respect of the proposals extant at that time for the 'partial deregulation of lasers and intense pulsed light sources', as presented in sections 3.10 to 3.13 of the 2008 consultation document.

We present below for your consideration our response to sections 3.48 to 3.52 of your current (30 March 2009) consultation document. We have framed our response according to the questions 3.1 and 3.2 as posed by your questionnaire (DH-97140), these being we believe the most closely relevant questions pertaining to the matters of concern to us. We should be grateful if you would kindly acknowledge safe receipt of this letter.

***Q3.1 Do the draft Regulations set out at Annex B accurately reflect the policy set out in Chapter 3 and Annex A?***

***Summary response to Q3.1:***

We note from sections 3.51 and 3.52 that the CQC does not intend to include 'non-surgical uses of lasers and intense pulsed light procedures within the scope of registration under the new system introduced by the 2008 Act'.

Instead, you indicate that you will work with 'sector and representative bodies on an alternative approach'. You further state that this development 'will occur over the next 18 months, so that alternative forms of regulation will be developed to support the provision of non-surgical lasers and lights procedures'.

We believe that the CQC is wise and prudent in its decision to allow time for careful analysis of the complex issues raised during the consultation process. ALSP would like to offer the CQC every assistance to support the smooth development of suitable regulatory procedures through to October 2010 and beyond.

**Detailed response to Q3.1:**

We wish to respond in detail to Q3.1 according to two major headings:

- **What** needs to be regulated: use of certain types of laser and intense light devices for certain types of treatment in the independent / private sector.
- **How** are these devices going to be regulated: the form the regulations should take.

**What needs to be regulated:**

1. The previous consultation (18 March 2008) sought feedback on the possible deregulation of non-surgical procedures only. Surgical procedures (including laser surgery in private hospitals and eye clinics) were to remain regulated as before. However it seems to us that if a new, more flexible and fit for purpose regime is to be developed then this should cover all applications, because the safety issues pertaining to lasers and intense light devices are essentially the same for both surgical and non-surgical applications. Thus there would be a generic scheme, but if necessary enforced by different agencies depending on the sector.
2. At a further level of detail, the question arises as to whether any new regulatory scheme will continue to apply (as per the current regulations) only to Class 3B and 4 lasers, and to intense light sources. One inconsistency here is that there are already devices used for skin treatment that have very divergent emission, and so are classified as Class 1M. There is also the proposed new Class 1C, having potentially Class 4 levels of emission but incorporating a contact sensor such that emission is only possible while in contact with the skin. If the philosophy underlying the current regulations were to be carried forward unchanged, Class 1C lasers would be excluded on the basis that they are not in Class 3B or 4. But since the main risk in the cosmetic sector is damaging the patient's skin by inappropriate or excessive treatment (rather than injuring staff via misdirected beams) this risk is not diminished one iota by a laser being Class 1C. This risk to the patient's skin is then main issue, albeit not the only issue, that needs addressing through some form of continuing regulation.
3. If the regulations (whatever form they take) were to continue to apply only to lasers in Classes 3B and 4, clinics using Class 1C lasers would be exempt from any form of oversight or control. Indeed, this would be a useful marketing claim by suppliers: 'use our Class 1C device to avoid the expensive and time-consuming hassle of registration, inspections, policies and procedures etc'. But patients could still be harmed in exactly the same way as when using Class 3B and 4 lasers or intense light devices.

4. In the light of our comments above, our suggestion for future regulation is that professionally used intense light sources (including lasers of any Class, and intense light devices of any Risk Group) that are used for affecting human tissue in the way intended for cosmetic skin treatments and hair removal, should be subject to regulation. The issue here is not the laser Class or intense light Risk Group per se, but the ability of the device to cause permanent scarring or pigmentation changes to the skin.
5. Currently we have somewhat 'overzealous' regulation imposing excessive and burdensome requirements. This needs to be pared down to something more appropriate and fit for purpose. In our proposal the new scheme would apply to all lasers and intense lights used professionally for these cosmetic procedures, regardless of the laser Class, or intense light Risk Group. The detailed procedures and precautions may differ depending on the Class / Risk Group (as indeed they ought to currently between Class 3B / 4 lasers and intense light devices). That is what a risk assessment is intended to sort out, but the requirement for some form of regulatory oversight should apply to all types of lasers and intense light devices.
6. Clarification is required of what the regulation will be in respect of laser dentistry. Again we have a situation where a variety of laser Classes are in use, such as for soft tissue treatment (e.g. to gums) using Class 3B lasers, and ablative hard tissue and photodynamic treatments using Class 4 lasers. The dividing line between cosmetic and non-cosmetic dentistry may be a difficult one to draw. However clearly some sort of control and regulation is needed in this sector as well.

**How are these devices to be regulated - the form the regulations will take:**

7. In general ALSP supports the 'MOT Model' proposed at the IHAS meeting held at Centre Point on 17 March 2009, chaired by Sally Taber. The main recommendations from the meeting were that the model should be:
  - self funding;
  - a statutory framework;
  - address the issue of unregistered premises – possibly by using civil fines;
  - lower cost to implement than current regime;
  - focus on the operator / user competency;
  - incorporate current guidance contained in DB2008;
  - include supplier responsibility issue;
  - require LPA reporting / audit;
  - be simple in approach and methodology;
  - reduce risks patients / public;
  - provide a licence;
  - identify possible primary regulatory authority;
  - identify how a third party can implement the schemeALSP would like to raise certain additional issues, as listed below.
8. Safeguards need to be put in place to prevent commercially led pressure on LPAs to be known as being less stringent than their competitors.

9. In respect of operator / user training, and given that this is now being seen as absolutely key to more fit for purpose regulation, we feel that more specific regulation is needed to control both course and tutor accreditation. This would cover both manufacturer / vocational training (i.e. how to actually carry out the treatments), as well as the more general laser / intense light safety training defined in the MHRA's 'Core of Knowledge' syllabus (see DB2008). In respect of Core of Knowledge training we suggest that consideration be given to different 'grades', as the needs (and often aptitude) of say a high street therapist offering only IPL hair reduction are somewhat different from those of e.g. a more medically oriented clinician offering laser skin resurfacing.

**Q3.2 If not, what changes are needed to the draft Regulations to ensure they reflect the policy set out in Chapter 3 and Annex A?**

**Response to Q3.2:**

Given that your current proposal is that regulations covering lasers and intense light devices will in fact be outside the scope of the CQC, but will instead be administered in some other way, we have not responded in detail to Q3.2. We feel that it has been more appropriate to concentrate our response on Q3.1, as above.

However we would like to make the following comment. We understand that the current CQC proposal is that, if no alternative regulatory body is tasked (or formed) to carry forward the regulation of non-surgical lasers and intense light devices, the default situation will be that all regulation of these devices will lapse from that date onwards. In our opinion this would not be a satisfactory outcome. Our view is that the default situation should be that, in the event of no alternative being found by October 2010, regulation should continue under the auspices of the CQC.

Yours sincerely,



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