



THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

PO Box 3785 Rhodes NSW 2138 Australia
Suite 2A Level 2 9 Blaxland Road Rhodes NSW 2138 Australia
Telephone +61 2 8765 0242 | Australia Only 1300 361 821
Facsimile +61 2 9736 2194 | Email admin@dermcoll.edu.au
Website www.dermcoll.edu.au

15 July 2015

Mr Peter Colgan
Manager, National Uniformity and Regulatory Systems
ARPANSA
PO Box 655
MIRANDA NSW 1490

By email: national_uniformity@arpansa.gov.au

Dear Mr Colgan

Consultation Regulatory Impact Statement (RIS) covering the use of Intense Pulsed Light sources (IPLs) and Lasers for Cosmetic or Beauty Therapy

Background and overview

The Australasian College of Dermatologists (ACD) is the training body for specialist dermatologists that is recognised and accredited by the Australian Medical Council. The ACD also provides education and training to GPs and allied health on matters relating to the skin. Cosmetic and beauty procedures and therapies involving use of IPL and lasers fall within the educational and training framework of ACD. The ACD training programme for dermatologists includes training in safe and judicious use of IPLs and lasers for both corrective and cosmetic-beauty indications. In Australia and abroad, dermatologists have a leadership role in the cosmetic-beauty laser/ IPL industry.

The ACD is concerned about the unnecessary injury to patients caused by inadequate training or substandard devices that are not TGA approved. Our college endorses a regulatory approach to ensure an acceptable level of safety in the cosmetic and beauty therapy industry for the benefit of all Australians. The document canvasses three options and we agree that option 3 – licencing of operators - appears most feasible. However, in the interest of a safer outcome for the community the ACD has several recommendations, including specific amendments to Option 3 (listed below). The ACD believes it is necessary to also extend regulation to cosmetic-beauty devices/ equipment itself, which currently falls outside of TGA regulation.

Our recommendations and suggested amendments to the licencing categories are listed below. All requested feedback within the RIS document is provided at the end of this submission. The ACD would be keen to continue our involvement in future discussions and committees relating to the above issues.

Recommendations

That the new regulations be supervised by the Australian Radiation Protection and Nuclear Safety Agency

New Legislation to:

1. Make illegal and punishable by prosecution using a Laser device Class 3b or class 4 /IPL that is not TGA approved.
2. Make illegal and punishable by prosecution - to sell a Laser device Class 3b or class 4 /IPL to anybody who cannot show a valid Australian laser/IPL license (once introduced).
3. Make it illegal and punishable by prosecution for children to be treated with laser or IPL except under supervision of Registered Medical Practitioners

Amendment to Categories 1-3

Category type	Qualifications and Practical Training required
<p>Category 1 <i>Licensed to operate laser/IPL for the following procedure: -Hair Reduction</i></p>	<ul style="list-style-type: none"> • Accredited IPL and laser safety course (unless incorporated into other qualifications). • Nationally recognised education and training from an Australian university or Registered Training Organisation in hair reduction that aligns to the specifications of a minimum level 7 as described in the Australian Qualifications Framework, or equivalent. <p style="color: red;">Alternatively RN or EN who have been intensively trained in an accredited Laser Practice for 18 Months as evident by their log book working under supervision of an Accredited Medical Practitioner</p> <p>Education must include:</p> <ul style="list-style-type: none"> ○ Clinical indications, common to hair reduction treatments, of different dermatological conditions can be identified ○ Hair reduction using class 3B laser, Class 4 laser or IPL <hr/> <p>➤ Hair reduction – minimal practical experience under supervision</p> <ul style="list-style-type: none"> ○ Minimum 50 hours ○ Practice different skin types ○ Clear log book
<p>Category 2 <i>Licensed to operate laser/IPL for the following procedures: - Vascular lesions - Pigmented lesions - Non-ablative skin treatments</i></p>	<ul style="list-style-type: none"> • Accredited IPL and laser safety course (unless incorporated into other qualifications). • Nationally recognised education and training from an Australian university or Register Training Organisation in skin therapies that aligns to the specifications of a minimum level 7 as described in the Australian Qualifications Framework, or equivalent. <p style="color: red;">Clinicians</p> <ul style="list-style-type: none"> • Clinicians who hold a bachelor of Health Sciences, or equivalent eg dermal clinician, nurse practitioner. • Clinicians must work under supervision of a registered medical practitioner * <p style="color: red;">Alternatively RN or EN who have been intensively trained in an accredited Laser Practice for 18 Months as evidenced by their log book working under supervision of an Accredited Medical Practitioner</p> <p>Education must include:</p> <ul style="list-style-type: none"> ○ Clinical indications of different dermatological conditions can be identified ○ Treatment of dermatological conditions using class 3B laser, Class 4 laser or IPL

	<ul style="list-style-type: none"> ➤ Vascular lesions – minimal practical experience under supervision <ul style="list-style-type: none"> ○ Minimum 70 hours ○ Practice different skin types ○ Practice different vascular conditions ○ Clear log book ➤ Pigmented lesions – minimal practical experience under supervision <ul style="list-style-type: none"> ○ Minimum 70 hours ○ Practice different skin types ○ Clear log book ○ Restriction that pigmentary conditions require clearance from a medical professional before treatment. This is to minimise possibility of inadvertently treating a potential cancer ➤ Non-ablative skin treatments – minimal practical experience under supervision <ul style="list-style-type: none"> ○ Treatment of acne, scarring and skin laxity ○ Minimum 70 hours ○ Practice different skin types ○ Clear log book
<p>Category 3 <i>Licensed to operate laser for the following procedures</i> - Skin resurfacing - Tattoo removal</p>	<p>Medical practitioners</p> <ul style="list-style-type: none"> • Current registration with the relevant Medical Board. • Accredited IPL and laser safety course (unless incorporated into other qualifications). <p>Clinicians</p> <ul style="list-style-type: none"> • Clinicians who hold a bachelor of Health Sciences, or equivalent eg. dermal clinician, nurse practitioner. • Accredited laser safety course (unless incorporated into other qualifications). <p style="color: red;">Alternatively RNs or ENs who have been intensively trained in an accredited Laser Practice for 18 Months as evidenced by their log book</p> <ul style="list-style-type: none"> • Clinicians must work under supervision of a registered medical practitioner as listed above <ul style="list-style-type: none"> • Skin resurfacing (ablative treatments) – minimal practical experience under supervision <ul style="list-style-type: none"> ○ Minimum 100 hours ○ Practice different skin types ○ Clear log book • Tattoo removal – minimal practical experience under supervision <ul style="list-style-type: none"> ○ Minimum 100 hours ○ Practice different skin types ○ Clear log book
<p style="color: red;">*Are required to possess a laser / IPL license</p>	

Requested feedback to the RIS document

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Stakeholders are invited to provide feedback on whether the nature and magnitude of the problem presented above is accurate. If not, please provide additional details to add to or correct the data in this section

The nature and magnitude of the problem uncovered by the study is likely to be accurate for moderate to severe complications. However, there is likely to be an underestimate for milder complications, as these will typically escape routine reporting and detection.

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Stakeholders are invited to provide their views on the significance of the problem in jurisdictions that do not regulate IPLs and lasers for cosmetic or beauty therapy.

This survey study is very helpful in estimating the magnitude of the problem. Even though the overall incidence of severe complications appears relatively low, there is nevertheless a significant monetary and productivity cost to the community. Further, with increasing accessibility and falling cost of laser devices coupled with increasing demand for cosmetic services from a larger pool of practitioners of varying expertise, the issues identified here (avoidable complications) are likely to amplify, underscoring the need for better regulations.

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Stakeholders are invited to comment on the options described above and suggest other feasible options to achieve the objective of reducing the number of serious injuries from the commercial use of IPLs and lasers.

Option 3 appears to be the most feasible. The national framework should include both IPL and lasers. Possibly other energy devices as they emerge particularly if they carry a risk of injury to patient and/ or practitioner.

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Stakeholders are invited to provide feedback on the assumptions used above to estimate the costs of consumer awareness campaigns, operator training and the production of guidance documents and the benefits of Option 1 (educational awareness)

The assumptions appear reasonable for the task.

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Stakeholders are invited to provide feedback on the assumptions used above to estimate the costs and benefits of Option 2 (self-regulation through a voluntary accreditation scheme)

The assumptions appear reasonable for the task.

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Stakeholders are invited to provide feedback on the percentage of the industry that has adequate qualifications and the assumptions used to calculate this compliance cost.

The assumptions appear reasonable for the task.

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Stakeholders are invited to provide feedback on the assumptions used above to estimate the costs and benefits of Option 3 (licensing of operators)

The assumptions appear reasonable for the task.

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Stakeholders are invited to comment on the expected competition effects, in particular whether Option 3 would result in significant restrictions to competition. Where possible, stakeholders are requested to provide data to support their views.

The assumptions appear reasonable for the task.

Stakeholders are invited to provide feedback on whether there is a sufficient case for government intervention based on the nature and magnitude of the problem.

Based the survey findings, we believe there is a reasonably good case for government intervention.

Yours faithfully

A handwritten signature in black ink, appearing to read "Chris Baker". The signature is fluid and cursive, with the first name "Chris" and last name "Baker" clearly distinguishable.

Associate Professor Chris Baker
President