Australian Government
Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement

Intense Pulsed Light sources (IPLs) and Lasers for Cosmetic or Beauty Therapy

Consultation Draft – May 2015

Comment on this consultation document should be forwarded by **31 JULY 2015** to:

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(Electronic submissions are preferred)

All submissions will be held in a register of submissions, and unless marked confidential, may be made public.

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Background

Lasers and Intense Pulsed Light (IPL) sources are devices used for a range of cosmetic purposes such as:

- removing hair,
- removing tattoos,
- removing birthmarks and various skin lesions,
- removing acne and acne scarring,
- treatment of vascular lesions,
- reducing the visibility of skin pigmentation,
- rejuvenating the skin.

Lasers and IPLs (sometimes also referred to as intense light sources or ILS) have now been in use in the cosmetic industry for a number of years. "Cosmetic" could be broadly defined as involving treatment of symptomatic (e.g. dark skin discolouration) and non-symptomatic (e.g. hair removal) problems of the skin for purely aesthetic reasons.

Lasers work by producing a beam of light that has a single wavelength. The beam of light produced can be focused on the specific area being treated. The laser beam selectively damages specific targets in the area being treated (e.g. capillaries, brown spots or tattoo pigment in the skin) allowing the area to be replaced by new cells or removed altogether depending on the desired treatment.

Lasers are classified according to the Australian/New Zealand Standard AS/NZS IEC 60825.1 *Safety of laser products Part 1: Equipment classification and requirements*. Typically, only Class 3B and Class 4 lasers have sufficiently high enough output to be used in medicine and beauty therapy. Class 3B and Class 4 lasers are capable of causing eye injury and can also cause skin burns.

Unlike lasers, IPLs produce a beam of broad-spectrum light, which may be pulsed and filtered to produce the desired cosmetic effect. The light produces more generalised effects on the skin, such as improvement in some forms of brown and red discolouration of the skin. IPLs are widely used in the hair removal industry.

1. Statement of the problem

Lasers and IPLs are used in a variety of medical and non-medical settings. The public perception of cosmetic medicine is that it is quick, easy, painless and with little risk, but many procedures are extremely complex and require a high level of surgical skill and aesthetic appreciation[1].

1.1 Nature and magnitude of the problems

(a) Missed or delayed diagnosis of skin cancers

Incorrect treatment using an IPL or laser by untrained or inexperienced operators can potentially remove or mask unrecognised or undiagnosed symptoms of melanoma or non-melanoma skin cancers. This could have serious consequences, including eventual death from skin cancers that are detected too late because an IPL or laser operator has masked a symptom of skin cancer.

[1] Orton, C. Regulating cosmetic surgery. BMJ (2002) 324: 1229-1230

The Radiation Health Committee (RHC) Working Group, which considered the use of laser and IPL devices for cosmetic purposes, conducted a voluntary, anonymous survey from 15 November 2012 to 13 December 2012 (the 2012 Survey) of registered health practitioners and non-medical practitioners in Australia seeking data on accidents/incidents caused by the use of lasers and IPLs. The detailed findings of the 2012 Survey are provided in Appendix B. The survey drew 430 responses from five medical practitioner groups (38%) and six other health and beauty practitioner groups (62%).

Responses by medical practitioners in the 2012 Survey showed that there were 62 cases in a 12-month period in which a diagnosis of skin cancer was missed or delayed because a pigmented lesion was incorrectly treated with an IPL or laser. Of the 62 cases there were 22 cases where diagnosis of a melanoma was missed or delayed. Melanoma is the most dangerous form of skin cancer with a highest mortality rate and early detection is crucial. Instead of being cut out, malignant lesions can be treated with a laser device, which represents a significant health risk with devastating outcomes for the patients. The response looked at skin cancers but there are potentially other cancers such as the removal of facial hair that may mask some hormone related cancers.

(b) Burns and permanent scarring

IPLs produce a large amount of heat at the target area of the skin. Localising the delivery of the heat can result in severe burns, blistering and scarring. In most cases the target areas can be quite large and as the effects of over exposure may only become apparent many hours after the treatment, there is potential for extensive permanent damage to the skin. The actual damage to patients would be bruising, swelling, burns or blistering and in some cases could lead to permanent scarring.

The responses to the 2012 Survey revealed a total of 416 injuries in the preceding 12 months, of which 268 were described as severe injuries, such as burns/blistering, permanent pigmentation changes and scarring.

(c) Permanent retinal damage

Lasers and IPLs are also hazardous to the eyes of both operators and clients. The power levels of light from IPLs and lasers are sufficiently high to cause permanent retinal damage if the light is directed at the eye.

Although the 2012 Survey reported only one case of eye injury in the preceding 12 months, the risk of accidental eye injury leading to permanent retinal damage is not insignificant as IPL and laser devices are increasingly being used for facial skin rejuvenation and acne treatment in the facial areas that are close to the eyes. This observation is supported by data from 59 NSW hospitals participating in an Emergency Department surveillance[2], which showed that 66 injuries from 2007 to 2012 for burns, blistering or erythema were associated with the improper use of a laser and four were associated with the inappropriate use of an IPL device. The data also showed that while all body regions were affected, the face was the most common area for reported injuries. Most of the 66 cases (80%) were in the semi-urgent or urgent category and one patient had to be admitted for critical care.

[2] Sourced from the Centre for Epidemiology and Evidence, NSW Ministry of Health

(d) Operator training

A wide range of operators provide services with IPLs and lasers. Many are qualified health professionals who are trained in the use of lasers and IPLs for cosmetic purposes such as dermal clinicians, dermatologists, cosmetic physicians and plastic surgeons but services are also provided by operators with limited or no training such as beauty therapists and tattoo removalists. Laser or IPL devices for cosmetic use are not approved by the Therapeutic Goods Administration (TGA) and are easily available on the Internet. The result is that a range of users both females and males, young to middle aged can receive cosmetic treatment using IPLs and lasers from operators who may undertake procedures without a proper understanding of the various risks that depend on the skin type (i.e. colour) of the person and the complexity of the procedure.

How a person appears after a treatment will depend on the type of treatment performed, all of which should be explained to them beforehand. This requires an understanding of the device and procedure being used for the treatment. For example, using IPL for skin rejuvenation may produce some mild, temporary redness and darkening and then flaking-off of freckles. Other treatments, such as laser treatments to remove birthmarks, may produce intense bruising and swelling. Still others, such as treatments for acne scarring, may produce intense swelling and redness with perhaps pinpoint bleeding and oozing. Proper explanation of the risks as well as the duration and severity of post-treatment conditions is critical. Proper training and qualification to understand the risks and effects of IPL and lasers on various skin types and the condition being treated is very important to ensure proper treatment management.

In its 2007 Annual Report, "The Office of the Victorian Health Services Commissioner" identified the use of lasers (including IPL sources) as an area of public interest and stated:

> *"Another cause for concern is the use of lasers by some beauty therapists to provide skin treatments and hair removal treatments. Neither the laser therapists nor the laser treatments are regulated in Victoria and the level of knowledge and skill among operators seems to be very varied. Lasers can be dangerous tools in untrained hands with potential to cause harm. Clients using these services have reported burns and scarring and hypopigmentation (permanent loss of pigmentation) resulting from these treatments where it seems the laser may not have been used correctly."*

Respondents to the 2012 Survey also provided information on the cause of an injury. For severe injuries (severe blistering, burns, scarring and permanent pigmentation change) respondents reported that more than 50% of the 268 severe injuries in the 12-month period the survey covered were training-related.

The problem is compounded by the fact that in some jurisdictions relevant training cannot be fully provided. For example, regulations in Western Australia do not allow anyone other than a doctor to operate a laser. Therefore when the nationally accredited SIB70110 Vocational Graduate Certificate in IPL and Laser Hair Reduction course is provided by a Western Australia-registered training organisation there is no laser component even though it is part of the curriculum, which means that a beauty therapist who wants to be trained in the use of lasers for hair reduction cannot do so in Western Australia.

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

1.2 Existing regulation

Currently, only Queensland, Tasmania and Western Australia regulate Class 3B and Class 4 laser operators. Non-medical professionals in Tasmania and Queensland need a licence to operate lasers for cosmetic purposes. In Tasmania a licence is also required to operate an IPL for non-medical use. In Western Australia, operators of laser devices must be registered medical practitioners. The remaining State or Territory jurisdictions have not introduced a regulatory framework to deal with the operation and use of lasers and IPLs.

The data from the 2012 Survey (see Table 14 of Appendix B) was analysed by State/Territory. Injuries in Queensland and Tasmania appear to be lower than the other jurisdictions that do not have any form of regulation whilst Western Australia has a higher rate of injuries. The low number of respondents to the survey makes it difficult to draw any conclusions. However, qualitative evidence from the Tasmanian radiation regulator is that in the first two years that non-medical IPL operators required a licence in Tasmania there were only two complaints and in both cases no breach or malpractice was found. The cases related to client expectations of the outcome or results of the treatment. This may suggest that licensing of IPL operators forces the operators to exercise due diligence and care for fear of losing their licence.

The 2012 Survey did not specifically ask respondents if they supported regulation for the operation of IPL and lasers by non-medical professionals but many respondents chose to voluntarily indicate their preference in the 'additional comments' section of the survey. A total of 144 (39%) respondents stated their support for regulations. The support was fairly evenly distributed between occupations.

The current training and qualification requirements for lasers and IPLs in the three States that regulate them are described below.

In Tasmania the Certificate of Compliance requires assessment of competency, qualifications and training. Licence applicants need to demonstrate that they have appropriate knowledge in IPL safety and are competent in using the equipment. Applications are considered on a case-by-case basis, as there are no nationally consistent training courses for cosmetic lasers and IPLs. Operators must also be supervised by a registered medical practitioner who has training and skills in the use of the types of lasers and IPLs authorised on the licence.

In Queensland a person must apply for a licence to use a Class 4 laser for medical and/or cosmetic purposes. Licence applicants need to provide a copy of formal qualifications or training certificates. Evidence of competency in the use of lasers is also required. Dermatologists require licensing to use a laser for therapeutic or cosmetic procedures. Persons seeking a licence to use a laser for hair removal are required to demonstrate an appropriate level of knowledge in laser safety and competency in the use of the laser. It is considered appropriate that persons who obtain a licence to use a laser for hair removal, and who are not medical practitioners, enlist the assistance of a medical practitioner.

In Western Australia the person operating a Class 3B or Class 4 lasers must have appropriate qualifications and experience. Medical practitioners working under the direction and personal supervision of a licensee may operate the laser. Personal supervision requires the licensee to be present on the registered premises.

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.

1.3 Case for intervention

The use of IPL and lasers for cosmetic purposes is increasing. The 2012 Survey showed that the 426 survey respondents for all the States and Territories who comprise a fraction of the total industry perform on average almost 736,000 procedures a year using IPLs and lasers.

As noted in section 1.1 above, the 2012 Survey shows that the even the relatively moderate 430 responses from five medical practitioner groups (38%) and six other health and beauty practitioner groups (62%) reported 416 injuries in the 12 months preceding the survey, of which 268 were severe injuries. It is estimated that approximately 10% of the industry responded to the survey. When extrapolated for the whole industry there are on average about 7 million procedures a year and potentially about 4000 injuries annually as a result of treatments.

The 2012 Survey also revealed that there were 62 cases in the same period in which a diagnosis of skin cancer was missed or delayed because a pigmented lesion was incorrectly treated by an IPL or laser. It is noteworthy that of the 62 cases there were 22 cases where diagnosis of a melanoma was missed or delayed, which signals a significant risk as melanoma is the most dangerous form of skin cancer with the highest mortality rate and early detection is crucial.

There is also the risk of permanent retinal damage from the use of IPL and laser devices for treatment in the facial areas. An estimate of the risk of permanent retinal damage was not possible from the 2012 Survey. However, as noted above, the data from 59 NSW hospitals showed that in a 5-year period to 2012 that the face was the most common area where injuries were reported from the misuse of an IPL device.

The lack of regulation has been a recurring theme in media reports. Two recent *Choice* magazine (Australian Consumers Association) articles on the use of IPLs and lasers for hair removal (May 2013) and tattoo removal (October 2013) highlighted the lack of government intervention. Other articles published in newspapers further highlight the injuries sustained by people and call for some form of government or regulatory intervention to protect consumers from unscrupulous operators. It is expected that this concern will not abate in the near future as commercial procedures using IPLs and lasers increase, especially in the area of tattoo removal. As a growth industry, an increase in tattoo removal procedures can present a risk of an allergic reaction in patients when the tattoo dyes break up, requiring medical intervention (See Appendix E).

While media articles are in themselves not necessarily conclusive basis for government intervention, when considered in conjunction with the results of the 2012 Survey and the more significant risks of masking melanoma skin cancers or the risk of permanent retinal damage, there appears to be a case for considering a range of intervention options for consumer protection.

The 2012 Survey also showed that of the 430 respondents only 38% were medical practitioners. Of the remaining another 138 were para-medical professionals, such as nurses and dermal therapists and another 105 were from occupations unrelated to the medical profession, for example, beauty therapists. The survey also showed that more than 50% of the 268 severe injuries in the 12-month period preceding the survey were training-related. Given the complexity of the skills required to carry out the procedures, it is arguable that the training and skill of the practitioner is critical in determining the outcomes of procedures and to that end there is a case to consider a range of intervention options for consumer protection.

2. Objective

The objective of government intervention is to reduce the incidents of serious injury among people receiving commercial treatment with lasers and IPL sources in cosmetic medicine and beauty therapy in a cost effective manner.

3. Statement of options

The following options have been identified for consideration:

Status quo: no change to current practices

Option 1: Educational awareness

Option 2: Self-regulation by industry/industry accreditation scheme

Option 3: Licensing (or registration) of service providers based on prior qualification and training

3.1 Status Quo – no changes to current practices

If the status quo is to be maintained, Queensland, Western Australia and Tasmania would be the only jurisdictions to have any control over who provides commercial services with lasers for cosmetic or beauty therapy. Tasmania is the only jurisdiction that currently regulates IPLs. Consumers in other jurisdictions would largely operate under the principle of *caveat emptor* ('let the buyer beware'). Consumer protection laws exist in all jurisdictions and there are two Australian Standards[3] which apply to the electrical classification of IPLs and lasers covering only the technical performance specifications of the equipment. However, the jurisdictions without any existing regulation will not have any form of controls over operator qualification and training to protect consumers; only a legal recourse may be available to the consumer after an injury has been sustained.

[3] AS IEC 60601.2.57:2014 *Medical electrical equipment Part 2.57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use,* and AS IEC 60601.2.22:2014 *Medical electrical equipment Part 2.22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*.

3.2 Option 1 – Educational awareness

This option relies on increasing public awareness of the potential hazards involved in cosmetic treatments using IPLs and lasers. The model aims to inform members of the public so that they can understand the importance of choosing a reputable provider, checking that the operator is qualified and is complying with all safety requirements. Under this scenario, safety guidance and practical advice would be published by ARPANSA through factsheets and brochures so that clients can be clearly informed about what expectations to have of providers.

The guidance would give advice and information on:

- Risks from exposure to IPL and laser radiation;
- Importance of client compliance;
- What treatments are appropriately provided by different sectors of the profession;
- Medical clearance for removal of pigmented lesions;
- Factors to look out for - indicators that an operator is not a credible operator;
- Importance of using quality equipment (approved by the Therapeutic Goods Agency (TGA) in cases where the apparatus may also be used for therapeutic purposes); and
- Recommended training of operator.

This option relies on the laser and IPL operator to voluntarily undergo training. The guidance material produced by ARPANSA would detail what training is necessary for particular procedures, as it can be difficult for inexperienced operators to ascertain the level of training that is suitable.

Under this model the relevant Australian Standards[4] for IPL and laser equipment performance would continue to apply. Relevant fair trading, consumer protection and trade practices laws as well as the common law of negligence would also continue to apply. The difference to the status quo is that the consumer will also be clearly informed about the risks and the precautions to exercise in selecting the type of treatments and the service providers.

The success of the model is contingent on effective public health campaigns to inform the public as well as to putting pressure on businesses to provide safe and appropriate treatments and procedures. It would also require industry associations to assist in the ongoing promotion of the safety guide.

3.3 Option 2 – Self-regulation by industry/industry accreditation scheme

Under this option industry would develop a safety guide for the commercial use of lasers and IPLs. This guidance information would support a voluntary accreditation scheme run by the industry.

This self-regulatory model would require the variety of cosmetic and beauty therapy providers across many industry sectors to agree to the standards for accreditation and consistently implement these standards. Such standards may include requirements and criteria for training, types of treatments that can be performed by different providers and medical clearance for certain conditions. This option is not mandatory and relies on the will of the industry to adopt and comply with the safety guide and the willingness of all service providers to take part in an accreditation

[4] *Ibid*

scheme that is not compulsory. To be successful, this option would require the majority of service providers to be members of participating professional organisations.

3.4 Option 3 – Licensing (or registration) of service providers based on prior qualification and training

This option involves the licensing of operators undertaking cosmetic and beauty therapy procedures using IPL and laser equipment.

Operators will be licensed only if appropriately trained and conditions may be imposed to ensure that referrals are made to medical practitioners under certain circumstances. More complex procedures like tattoo removal and skin resurfacing could be restricted to medical practitioners, or clinicians working under the supervision of a registered medical practitioner. Certain pigment conditions would require clearance from a medical professional before treatment.

Qualifications and training would form the basis of licensing. Treatment types would be divided into three categories depending on procedure complexity. Licences will state which procedures the operator is licensed to perform. Anyone who fulfils the qualifications for a certain category will also be deemed able to fulfil the qualifications for the categories below it. However, the operator will be required to fulfil the requirements for practical training for each procedure that they wish to be licensed to perform.

Appendix A describes Option 3 in detail.

The Tasmania and Queensland requirements are similar to the training level requirements in Appendix A – Description of Option 3. Whilst Option 3 distinguishes between various treatments and their requirements, the various state regulations are not as distinct.

In Tasmania the main requirements for a licence applicant using IPL and lasers for cosmetic purposes are competency, qualifications, training and appropriate knowledge in safety. Supervision by a registered medical practitioner is also required.

In Queensland only applicants using Class 4 lasers for medical and cosmetic purposes must apply for a licence. IPLs are not regulated. Evidence of qualifications, knowledge of laser safety and competency is required. Supervision by a registered medical practitioner is also required.

In Western Australia only operators of Class 3B and Class 4 lasers must have appropriate qualifications and training. Supervision is a requirement.

The three states which regulate lasers would need to amend their regulations to accommodate the different categories. The requirement for qualifications, training and laser safety knowledge that exist in the current state regulations are also a requirement for Option 3. In Option 3 supervision to achieve the minimal practical experience is a requirement similar to the states that regulate lasers.

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.

4. Impact analysis (costs and benefits)

4.1 Affected stake holders

The main affected stake holder groups are:

(a) Regulatory agencies in each State and Territory and the Commonwealth.

(b) Operators of lasers and IPLs in the cosmetic industry. These include, but are not limited to: beauty therapists, dermal clinicians, cosmetic physicians, plastic surgeons and tattoo removalists.

(c) Registered health professionals who do follow-up work on failed procedures: general practitioners, cosmetic surgeons, plastic surgeons etc.

(d) Consumers exposed to laser and IPL radiation when undergoing cosmetic procedures.

4.2 Impact analysis for keeping status quo:

Under this approach there is no change to existing practices. Lasers are regulated only in Tasmania, Queensland and Western Australia and IPLs are regulated only in Tasmania. The number of injuries and adverse outcomes may increase because the equipment, in particular IPLs are becoming cheaper and more easily available and the number of procedures being performed is increasing. As it is difficult to estimate the rate of this increase, the cost estimate below is based on an assumption that the number of injuries and adverse outcomes will be constant over the years. The costs for this option are medical costs and the cost of lost working time due to injuries sustained from IPLs and laser treatments. The costs are summarised below.

4.2(a) *Cost – Medical costs*

The health costs are estimated from the number of injuries and medical cost associated with these injuries. Based on information obtained in the IPL and Laser survey (see Appendix B) there are 2,680 severe and 1,480 minor injuries annually across Australia (values taken from Table 9 and multiplied by 10 as we estimate that we have surveyed 10% of the industry). The medical costs for treating severe injuries range from $1.25 to $2.18 million and the medical cost for treating minor injuries range from $0.07 to $0.21 million. This results in an annual cost ranging from $1.32 to $2.39 million.

4.2(b) *Cost – Work time lost*

There is a significant cost to society due to the loss of work time. For severe injuries the total number of workdays lost is 910 days for less than one day and 14607 for more than one day. For minor injuries there are no loss of work time less than one day and 1027 for more than one day. In total, this corresponds to a range of 4 to 65 person years. Based on a cost of $303/day this corresponds to a cost ranging from $0.28 to $4.74 million.

Appendix C provides more details of the costs of maintaining the Status Quo.

4.3 Impact analysis for option 1 (educational awareness):

Costing for this option has been done in a general manner only. The largest cost component for this option will be for the consumer awareness campaign. There is a range of ways a consumer campaign can be run. In a well-designed and targeted campaign more money spent will result in better

outcomes. The numbers given below are estimates of the costs and effectiveness of the campaigns. The laser and IPL awareness campaign would be directed to the over-18 age group and would primarily be directed towards women. Although a number of men undergo IPL and laser treatments for hair-reduction, the majority of the clients are women. The awareness campaign would not seek to change behaviour in the way anti-smoking campaigns and healthy eating campaigns do. The aim is instead to inform potential clients so that they have the knowledge to make sensible choices when choosing a provider. The important message for the client from an awareness campaign is that there is the possibility of injury when undergoing IPL or laser treatments. Having well informed clients will indirectly put pressure on providers to provide safe and appropriate treatment.

4.3(a) Costs of consumer awareness campaigns:

Educational campaigns have led to substantial behavioural modification in the area of UV exposure over the last few decades. Various 'Sun Smart' type campaigns have had a large impact on people's behaviour in relation to sun exposure.

Based on other public campaigns an amount of $15 million to $20 million can be expected to be spent on an effective public awareness campaign. This would consist of advertising in magazines, on radio, online and through professional organisations. It is expected that the educational awareness program would be repeated every two years to ensure that the message is reinforced effectively.

Costs to businesses are expected to rise as service providers would, in response to more informed consumers, be more likely to voluntarily undertake training to acquire recognised qualifications. It is difficult to estimate the expected demand for training but on the assumption that there is a 30% uptake in training with a 15% average turnover, the costs would range from $0.33 to $0.64 million.

4.3(b) Costs of producing guidance document:

Guidance promulgated by ARPANSA would inform consumers and operators on standards that are expected to be upheld by service providers. This guidance would be based on the international guidelines for use of IPLs (IEC/TR 62471-3 *Safety of intense pulsed light source equipment – Guidelines for the safe use of intense pulsed light source equipment on humans*) and the Australian Standard AS/NZS 4173 *Safe use of Lasers in Health Care*.

A safety guide based on the international guidelines may be published by ARPANSA. If this is necessary, there will be some cost to ARPANSA to produce this guidance material but its cost has not been included in this RIS because it is a one-off cost and ARPANSA's current functions include the publishing of relevant safety guides, factsheets and guidance material.

4.3(c) Benefits of educational awareness:

The benefits will be in improved health outcomes with a reduction in the number of injuries. An estimate by the RHC working group is that an effective educational campaign could decrease the injury numbers by 10% to 30 %. This would correspond to a cost benefit of $0.40 to $0.72 million in medical costs and $0.08 to $1.42 million in loss of working time if a 30% decrease was achieved.

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)

4.4 Impact analysis of option 2 (self-regulation):

As mentioned in 3.3 above, under this option industry would develop a safety guide for the commercial use of lasers and IPLs. This guidance information would support a voluntary accreditation scheme run by the industry. Operators who wish to be accredited would have to gain the appropriate qualifications by undertaking the prescribed training. The clients need to be aware of the potential risks from IPL and laser treatments for self-regulation to work. Well informed consumers can put pressure on providers to become accredited.

4.4(a) Cost of training

The costs to the industry will be mainly from the need to train operators so that they fulfil the minimum competency requirements to use lasers and IPLs for cosmetic procedures. An accredited IPL and laser safety course required to provide adequate education and training would cost approximately $2,500 to $3,500 per person. Estimating the overall costs is difficult as it depends on participation by the operators. The training costs based on a 10% to 20% (average 15%) turnover and only 20% participation would range from $0.22 to $0.47 million.

4.4(b) Benefits

The RHC working group felt the health and work time gains from self-regulation could decrease the injury numbers by 10% to 20 % similar to using an educational campaign. This would correspond to a cost benefit of $0.24 to $0.48 million in medical costs and $0.47 to $0.95 million in loss of working time.

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)

4.5 Impact analysis for option 3 (licensing of operators)

This option requires licensing for all cosmetic procedures using lasers and IPLs. Complex procedures like tattoo removal and skin resurfacing will be restricted to medical practitioners, or clinicians working under the supervision of a registered medical practitioner. Certain pigment conditions will require clearance from a medical professional before treatment. Option 3 has been described in detail in Appendix A.

Compliance costs for businesses:

4.5(a) *Costs* of additional training required:

The costs to the industry will be mainly from the need to train operators so that they fulfil the competency requirements set out in option 3. The cost is estimated below, where possible, for the different occupational categories.

1) Accredited IPL and laser safety course:

Based on a staff turnover of about 15% in the beauty therapy industry and an estimated cost of $2,500 to $3,500 per person for an IPL and laser safety course, the estimated cost of additional training is $1.06 to $2.26M. The course can be done on a part-time basis which means that there will be no loss of working time.

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.

2) Professional qualifications required:

Beauty therapists:

The beauty therapy industry is a transient industry. The average professional lifespan of a beauty therapist is estimated to be approximately 5-10 years. This means that each year there is a 10-20 % turnover. The beauty therapists entering the industry would require the following training. (Appendix A).

Training in hair reduction (category 1) required:

Data obtained in our survey of the industry show that 15% of beauty therapists (this includes laser therapists) do hair reduction only. The remainder do other procedures also and will need training in skin therapies (category 2).

It is estimated that the cost of the course is approximately $2,500

Training in skin therapies (category 2) required:

85% of beauty therapists (this includes laser therapists) do category 1 and category 2 procedures and will require this training.

The cost of the course is estimated to be $3,500.

Both the courses above are done on a part-time basis, which means that there will be no loss of working time.

*Note the cost for full Advanced Diploma courses over 12 to 18 months duration in Beauty and Laser Therapies range from $12900 to $17900.

Dermal clinicians:

All assumed to have appropriate training.

Medical professionals:

All assumed to have appropriate training.

4.5(b) Licensing costs for businesses:

Number of IPL and laser operators:

The number of IPL and laser operators in Australia in the cosmetic industry has been estimated through a few different methods.

From the survey we estimate that there are 4,000-5,000 operators in Australia.

According to estimates provided by insurance companies and a representative on the RHC working group there are 4,000-4,500 qualified beauty therapists and dermal therapists who use IPLs and lasers.

In Tasmania both IPLs and lasers are regulated. If the number of IPLs and lasers in Tasmania is extrapolated to cover the whole of Australia, purely based on population, the total number of operators of IPLs and lasers will be 2,600. This is quite low compared to other estimates. Tasmania has quite a different demographic; the population is more rural and there is less sun damage. This could explain why the numbers of operators is smaller than expected once the values are extrapolated to the whole of Australia.

From the estimates above we assume that there are 2,600 – 5,000 operators in Australia.

A small number of these are already licensed:

- 57 cosmetic laser and IPL use licences in Tasmania
- 308 cosmetic laser use licences in QLD
- Lasers are regulated in Western Australia, but as the licence does not explicitly state if the use is cosmetic or medical we do not have an exact number.

A reasonable estimate is that approximately 500 operators are licensed under current regulations.

This number has been subtracted from the total number, which leaves 2,100 – 4,500 operators who will experience an additional licensing cost. Assuming a cost of $300/year per licence the cost will be $630,000 – $1,350,000.

*Note that as the cost structure varies in the different states the cost of the existing licenses will vary and can be more or less than $300. Application and licence fees for both the Queensland Department of Health and the Tasmanian Department of Health and Human Services are available on their web sites. Tasmania has an application licence fee of $125.80 (payable only once), licence charges to use a radiation apparatus $125.80 and licence to possess and use 1 radiation apparatus $202.76 (minimum annual licence cost). Queensland charges a licence fee for possession of a laser $648 (includes one off $412.50 application fee) and an annual licence fee for using laser $141.50 (includes one off $82.50 application fee).

4.5(c) Cost to consumers:

The increased costs of compliance for businesses are expected to be passed on to consumers. Procedures will become more expensive as some operators will need additional training and there is a licensing fee to be paid by the operator. It is assumed that the full cost of compliance for the business is passed on to the consumer. No additional cost has been attributed to the consumer as the compliance costs calculated above are already accounted for.

Certain operators might choose not to, or not have the capacity to, undertake further studies to fulfil the competency requirements. This might include operators who have set up their business in a temporary way where profits are reliant on cheap equipment and low qualifications of the operator. These operators might discontinue their businesses and this could temporarily restrict competition. However, the discontinuation of such services is beneficial for consumers as it is likely to result in safer procedures and less injuries.

4.5(d) Cost – Regulatory agencies:

It is assumed that the regulatory costs will be recovered by the regulatory agencies through licence fees. Therefore no additional costs will be incurred by the regulatory agencies.

4.5(e) Cost – Legislative costs:

There is a cost associated with amending the legislation to allow for regulation of lasers and IPLs in some States and Territories. This is a one-off cost and will not have any impact on the industry or consumers. It is also an administrative cost not normally included in the regulatory impact statement.

4.5(f) Benefits – Health

The health benefits are estimated from the reduction in the number of injuries and medical cost associated with injuries caused by lasers and IPLs. Based on information obtained in the IPL and Laser survey outlined in the section on keeping the status quo the medical cost ranges from $1.32 to $2.39 million. By introducing regulations the RHC working group agreed that a reasonable estimate of 50% to 90% for the reduction of injuries and that during the transitional period the lower number might be applicable and once regulations have been in place for a few years a reduction in injuries would be closer to the higher value. This amounts to a benefit of $0.66 - $1.19 million to $1.20 - $2.15 million.

4.5(g) Benefits – Work time gained

The loss of work time due to injuries from IPL and lasers results in a significant cost to society. Loss of work time due to injuries currently amount to $0.28 to $4.74 million as outlined above in the section on keeping the status quo. Based on a reduction of injuries by 50% to 90%, the work time lost will be reduced by the same amount. This will amount to a cost benefit of $0.14 - $0.25 million during the transition period and once regulations have been in place for a few years potentially $2.37 - $4.26 million.

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

5. Comparison of options

The costs and benefits of the three identified options (option 1, 2 and option 3) in comparison with the status quo are presented below. Some of the costs are one-off (training) and some of the costs are annual (licensing costs). To aid comparison, the estimated costs and benefits have been converted into net present values (NPV) assuming a forecast period of 10 years and a discount rate of 7 per cent. (Calculations are in Appendix D – Options Compared)

Options	Status quo Annual amount ($ million)	Option 1 (educational awareness) Annual amount ($ million)	Option 2 (self- regulation) Annual amount ($ million)	Option 3 (regulation) Annual amount ($ million)
COSTS				
Costs of consumer awareness campaigns	-	$15 to $20	-	-
Compliance costs for business				
Cost of additional training required	-	$2.47-$4.80	$1.65-$3.54	$7.91-$16.96
Cost of licensing	$0.14-$0.48	-	-	$4.72-$10.12
Cost to consumers	Already included in business costs			
Cost to regulatory agencies				Recovered through licensing
Costs - legislative changes	Generally not costed in RIS			
Total costs	**$0.14-$0.48**	**$17.47-$24.80**	**$1.65-$3.54**	**$12.63-$27.08**
BENEFITS				
Benefits - Health				
Medical costs avoided	-	(10%-30% decrease) $0.99-$5.38	(10%-20% decrease) $0.99-$3.58	(50%-90% decrease) $4.95-$16.13
Loss of work time avoided	-	$0.21-$10.66	$0.21-$7.10	$1.03-$31.97
Total benefits	**-**	**$1.20-$16.04**	**$1.20-$10.68**	**$5.98-$48.10**
NET IMPACT	**-**	**$16.27-$8.76**	**$0.45-$7.14**	**$6.65-$21.02**
Lowest benefit – highest cost	-	$1.20 - $24.80	$1.20 - $3.54	$5.98 - $27.08
Highest benefit – lowest cost	-	$16.04 - $17.47	$10.68 - $1.65	$48.10 - $12.63

6. Competition effects

Maintaining status quo would not adversely affect the level of competition in the market.

The options of self-regulation in the industry (option 2) or providing consumers educational awareness (option 1), would have a negligible effect on competition as the voluntary nature of those options means that businesses would not actually face a barrier to entry.

As qualifications and training form the basis of licensing for Option 3, this option would create a barrier to entry and this may arguably have the effect of reducing competition and possibly increasing prices as the number of practitioners available to provide the services may reduce in the short run. However, this restriction to competition is also likely to ensure that the service providers who stay in business (because they have or acquire the necessary training) or those who enter the marketplace with the proper qualification and training are also those who are likely to offer safer treatment with IPLs and lasers to consumers seeking cosmetic or beauty therapy with those equipment. It is considered that while there may in the short run be a restriction to competition under Option 3, the benefits of this restriction would outweigh costs through better consumer protection.

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.

7. Consultation

The initial consultation process began with members of the RHC working group, which was established by the Radiation Health Committee to examine options for how lasers and IPLs can be used safely in the cosmetic industry in Australia. The RHC working group consists of government radiation and health representatives, medical practitioners and representatives from organisations who have members working in the cosmetic industry. In 2012 a survey was undertaken to obtain an estimate of the number of cases of injury and mistreatment in cosmetic treatments using IPLs and lasers across Australia. Appendix B provides the scope and methodology adopted for the survey.

This consultation RIS is based on the views of the RHC working group as well as the findings of the survey. The final decision RIS will take into account comments and feedback received from all stakeholders who respond to the public consultation.

This consultation and decision RIS will be made available on the ARPANSA website at www.arpansa.gov.au.

In addition to an advertisement in a national newspaper, a range of organisations including the following will be advised of the availability of the consultation RIS and their comments will be requested:

- Radiation Regulatory Authorities in all jurisdictions,
- Professional societies and associations (Cosmetic Physicians Society Australasia, Australian Society of Dermal Clinicians, Association of Professional Aestheticians of Australia, Advanced

Association of Beauty Therapists, Aesthetics Practitioners Advisory Network P/L, Australian College of Dermatologists, Australian Medical Association, Royal Australian College of General Practitioners, Australian College of Cosmetic Surgeons, Australasian College of Aesthetic Medicine, Australasian College of Cosmetic Medicine, Australian Society of Plastic Surgeons, Australian College of Nursing, Australasian College of Physical Scientists and Engineers in Medicine, Australasian Radiation Protection Society),

- Radiation Health and Safety Council, the Nuclear Safety Committee and the Radiation Health Committee,
- Radiation Councils and Advisory Councils in all jurisdictions,
- Commonwealth, State and Territory Government Departments, Agencies and Committees involved in health protection and public health and safety.

8. Evaluation

As this is a consultation RIS, the RHC working group would like to receive feedback on options 1, 2 and 3. However, in order to assist in the discussion, the RHC working group would like to share with stakeholders its preliminary evaluation.

Option 1 (educational awareness) relies on providing sufficient information through public health campaigns to empower consumers to be aware of the risks of cosmetic treatment with IPLs and lasers and to be able to make informed choices in selecting treatments and properly qualified service providers. By empowering consumers it is hoped that service providers would voluntarily seek and obtain the appropriate training and qualification, but there is no way of ensuring that this happens.

Option 2 (self-regulation through voluntary accreditation) also relies on the will of the industry to adopt and comply with a safety guide or standard produced by the industry. For this model to be successful enough operators must belong to a professional organisation and the professional organisation needs to be influential. It is possible that some industry bodies will decide not to participate. For operators that are unlikely to join a professional organisation, there is no incentive to comply with non-mandatory standards. In this regard, the RHC working group notes that a recent review by the UK Department of Health found that self-regulation in the industry has failed. The report[5] found that:

> "*Previous attempts at self-regulation in the (cosmetic intervention) industry have failed, largely because voluntary codes have meant that only the best in this disparate sector commit themselves to better practice, whilst the unscrupulous and unsafe carry on as before*" [6]

Option 3 (licensing on the basis of training and qualification) can potentially reduce serious injuries from the use of IPL and laser for cosmetic treatments as operators will be required to have practical training for the procedure they wish to be licenced to perform.

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[5] *Review of the Regulation of Cosmetic Interventions*, UK Department of Health (April 2013) (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf)

[6] *Ibid,* p.5

It is acknowledged that option 3 involves costs to industry related to training and authorisation of operators and the assessment of the suitability of a patient for treatment by a medical practitioner. However there is greater likelihood that the risks highlighted in section 1 above in relation to burns, scarring and retinal damage and, in particular, the risk of masking skin cancers or melanomas could be minimised with an intervention that tries to ensure that service providers are appropriately trained and qualified.

There is also evidence that a regulatory approach is preferred overseas. For example, a regulatory framework is currently being considered in the UK, where controls over lasers and IPLs are currently regional. However, the 2013 UK Department of Health review of the regulation of cosmetic interventions has made recommendations for registration of practitioners, including those using lasers and IPLs. The review recommended that everyone "performing cosmetic interventions must be registered" and the Government's "mandate should include the development of appropriate accredited qualifications for providers of non-surgical interventions…..".[7]

9. Implementation and Review

Whichever option is implemented, it will be proposed to be done in a nationally uniform manner. It is agreed that each jurisdiction could manage this issue in its own way but, particularly for matters such as this where training is marketed to a national audience, equipment and treatments are marketed to a national audience and the problems in jurisdictions are all similar, the experience of jurisdictions is that such matters are most efficiently managed in a nationally consistent manner. This approach is consistent with the goals of the Final Report of the National Competition Policy (NCP) Review of Radiation Protection Legislation (2001) which recommended that jurisdictions are to implement radiation protection policies and practices in a nationally uniform way. The recommendation was endorsed by the Australian Health Ministers' Conference. Amongst other things, consistency between jurisdictions will facilitate the ability to form standards accepted in all jurisdictions, for training that is acceptable in all jurisdictions and for the seamless recognition of qualifications, skills and expertise in all jurisdictions.

Should option 1 (education and awareness) be recommended and accepted, the development and dissemination of guidance material will be implemented by ARPANSA through the Radiation Health Committee (RHC). The States and Territories would still be responsible for the dissemination of the guidance material but the development and publishing of the guidance material would be coordinated by ARPANSA and endorsed by the RHC.

It also appears that option 2 can be implemented in a national uniform manner. Should option 2 be recommended, the relevant industry organisations may be able to agree on a nationally consistent approach.

Should option 3 be recommended, the proposed model for the licensing of service providers will be recommended to the Council of Australian Governments (COAG) Health Council. Upon approval by the COAG Health Council, the agreed model would be published in the *National Directory for Radiation Protection* (NDRP), which would provide the requirements that each State or Territory

[7] *Ibid,* p.7

must implement in its jurisdictions. Whichever option is implemented, it will be reviewed by the Radiation Health Committee after 10 years to ensure that it remains consistent with international radiation protection practice. Earlier review will be undertaken if there are problems with implementation, if international radiation protection objectives change or new scientific information becomes available.

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.

Appendix A – Description of option 3

Qualifications and training forms the basis of licensing. Procedures have been divided into three categories: 1, 2 and 3 depending on the complexity of the procedure and the qualifications required. The licence will state which category type the operator is licensed to perform and the operator is licensed to perform all procedures belonging to that category.

Anyone who fulfils the qualifications for a certain category is also deemed to fulfil the qualifications for the categories below, i.e. if someone is qualified to do category 2 procedures; they are automatically qualified to do category 1 procedures. The operator will be required to fulfil the requirements for practical training for each procedure that they wish to be licensed to perform.

With category 3 procedures clinician must have adequate personal professional indemnity insurance and patient must understand and consent to the procedure.

There is no distinction whether the procedure is performed using a laser or an IPL on the licence.

Category type	Qualifications and Practical Training required
Category 1 *Licenced to operate laser/IPL for the following procedure:* *-Hair Reduction*	· 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. Education must include: o Clinical indications, common to hair reduction treatments, of different dermatological conditions can be identified o Hair reduction using class 3B laser, Class 4 laser or IPL
	Ø Hair reduction – minimal practical experience under supervision o Minimum 50 hours o Practice different skin types o Clear log book
Category 2 *Licenced to operate laser/IPL for the following procedures:* *- Vascular lesions* *- Pigmented lesions* *- Non-ablative skin treatments*	· 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. Education must include: o Clinical indications of different dermatological conditions can be identified o Treatment of dermatological conditions using class 3B laser, Class 4 laser or IPL

Category type	Qualifications and Practical Training required
	Ø Vascular lesions – minimal practical experience under supervision o Minimum 70 hours o Practice different skin types o Practice different vascular conditions o Clear log book Ø Pigmented lesions – minimal practical experience under supervision o Minimum 70 hours o Practice different skin types Clear log book o Clear log book o Restriction that pigmentary conditions require clearance from a medical professional before treatment. This is to minimise possibility of inadvertently treating a potential cancer Ø Non-ablative skin treatments – minimal practical experience under supervision o Treatment of acne, scarring and skin laxity o Minimum 70 hours o Practice different skin types o Clear log book
Category 3 *Licenced to operate laser for the following procedures* *- Skin resurfacing* *- Tattoo removal*	**Medical practitioners** · Current registration with the relevant Medical Board. · Accredited IPL and laser safety course (unless incorporated into other qualifications).
	Clinicians · Clinicians who hold a bachelor of Health Sciences, or equivalent eg. dermal clinician, nurse practitioner. · Accredited laser safety course (unless incorporated into other qualifications). · Clinicians must work under supervision of a registered medical practitioner as listed above.
	· Skin resurfacing (ablative treatments) – minimal practical experience under supervision o Minimum 100 hours o Practice different skin types o Clear log book · Tattoo removal – minimal practical experience under supervision o Minimum 100 hours o Practice different skin types o Clear log book

Appendix B – IPL and Laser Survey

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Executive summary

A working group was established by the Radiation Health Committee (RHC) in 2012 to examine options for how intense pulse light sources (IPLs) and lasers can be used safely in the cosmetic industry in Australia. Any regulatory proposal will have to be backed up by clear evidence of injuries; the difficulties in obtaining sufficient injury statistics have hampered earlier attempts to introduce regulation. This report conveys the results from a survey that was undertaken by the RHC working group to establish up-to-date statistics of injuries and cases of mistreatment. The main concerns are burns, blistering and infections which can lead to permanent scarring. There is also concern that pigmented lesions are treated inappropriately, leading to skin cancers not being diagnosed and treated.

A link to the online survey was distributed via e-mail to operators in the field. The contact network of the members of the RHC working group was used to reach operators. The recipients were encouraged to complete the survey if they work with lasers or IPLs for cosmetic purposes, or if they have treated injuries caused by them. Respondents were asked to account for any cases of injury or mistreatment that they had encountered in the past 12 months.

It is estimated that approximately 10% of the industry was surveyed and reports were received of 416 cases of injury. In 268 of these cases, the injury was classified as severe. However, a large number of procedures are being performed so as a percentage the injury rate is still relatively low. In most cases the injury rate is below 0.1 %.

The respondents reported 62 cases where diagnosis of skin cancer was delayed or missed due to a pigmented lesion being inadvertently treated. In 22 of these cases the cancer was a melanoma, which is the most dangerous form of skin cancer.

The report acknowledges that the conducted analysis has limitations in that there is a possibility of false data being entered and a possibility of double counting. There is also the potential of over-representation of responses by operators concerned about injuries and mistreatment. The aim of the survey is to give an approximate estimate of the number of injuries, not absolute numbers. We believe that the limitations are acceptable for this type of survey and the results are useful to provide guidance on whether regulatory action is justified.

1. About the survey

1.1 Background

In recent years there has been growing concern that lasers and intense pulse light sources (IPLs) are used inappropriately in the cosmetic industry. There have been a number of reports in the media of injuries caused by improper use of lasers and IPLs, which has resulted in calls from the cosmetic industry that regulation should be introduced. The main concerns are burns, blistering and infections which can lead to permanent scarring. There is also concern that pigmented lesions are treated inappropriately, leading to skin cancers not being diagnosed in a timely manner.

The Radiation Health Committee (RHC) appointed a working group in 2012 to examine various options to ensure that IPLs and lasers used for cosmetic purposes are used safely across Australia. The objective of the project is to ensure that a suitable uniform approach is taken across all jurisdictions to ensure that IPLs and lasers are used appropriately and the risk for injury and mistreatment is minimised. Currently, lasers used for cosmetic purposes are regulated in Queensland, Tasmania and Western Australia. Regulation of IPLs has recently been introduced in Tasmania.

This survey has been undertaken in order to obtain an estimate of the number of cases of injury and mistreatment.

1.2 Scope

The objective of the survey was to gather evidence of injury and mistreatment in cosmetic treatments using IPLs and lasers across Australia. The cosmetic treatments consisted of hair reduction, skin rejuvenation, treatment of vascular lesions, treatment of pigmented lesions, treatment of acne and other forms of scarring or striae, resurfacing and tattoo removal. Cosmetic surgery was not included in the scope. The survey related to injuries caused during the 12 months leading up to the survey.

1.3 Methodology

The survey was conducted using 'Survey Monkey' (www.surveymonkey.com). An e-mail with a link to the survey was sent out to various professional networks, using the contact network of the members of the RHC working group. Recipients were encouraged to complete the survey if they work with lasers or IPLs for cosmetic purposes, or if they have treated injuries and mistreatments caused by them. The survey was distributed to the following professional associations:

- *Advanced Association of Beauty Therapists*
- *Cosmetic Physicians Society Australasia*
- *Australian Society of Plastic Surgeons*
- *Australasian Society of Cosmetic Medicine*
- *Australasian College of Aesthetic Medicine*
- *Australian College of Cosmetic Surgeons*
- *Royal Australian College of General Practitioners*
- *Australian Medical Association*
- *Australian Society of Dermal Clinicians*

Australasian College of Dermatologists
Aesthetics Practitioners Advisory Network P/L
Association of Professional Aestheticians of Australia

We also asked the radiation regulators to distribute the survey in the states where lasers are regulated. These are:

Department of Health and Human Services (DHHS) – Tasmania
Radiological Council – Western Australia
Queensland Health – Radiation Health Unit

The survey was open for four weeks (15 November – 13 December 2012). Respondents were asked to account for any injuries or cases of mistreatment they had encountered in the last 12 months. The first section of the survey dealt with adverse outcomes that the operator had caused themselves (these are referred to 'self-reported' injuries or adverse outcomes in the report). The second part of the survey was related to adverse outcomes caused by another operator, but treated by the respondent (these are referred to 'treated' injuries or adverse outcomes in the report). The third part of the survey was directed towards medical practitioners only, and requested information relating to the inadvertent treatment of a pigmented lesion resulting in delayed or missed diagnosis of skin cancer.

The survey was anonymous, with an option for the respondent to enter their contact details.

There are certain limitations of the survey which include:

- *False data being entered* – With any survey there is a possibility that respondents enter false data. As the survey was anonymous there is no possibility of verifying the data that has been entered. This issue was discussed extensively in the RHC working group. It was considered that anonymity was necessary to ensure that members of the medical profession would participate in the study. Respondents are also more likely to disclose that they have caused injuries if they have the option of doing it anonymously. The IP address was recorded for each respondent and only one response was accepted from each IP address. We found that there were a high percentage of respondents who left contact details. This is encouraging and indicates that many operators are comfortable with disclosing information about injuries they have caused.

- *Double counting* – The same injury might be reported by the person causing the injury and by a person treating the injury. As we have surveyed a relatively small section of the industry (estimated 10%) double counting is not expected to influence the results in a significant way.

- *Skewed representation* – Operators who are concerned about injuries and mistreatment are more likely to respond to the survey. We have distributed the survey through professional networks and radiation regulators where lasers and IPLs are regulated. Using the professional networks we were able to canvas a larger proportion of cosmetic practitioners then would have been otherwise possible. Without support of the professional networks the percentage of respondent may have been even lower. Using the professional network would have canvassed a larger proportion of operators then relying on the web only. But, it is likely that we have not canvassed the opinions and collected data from operators that are not part of professional networks.

Obtaining accurate numbers of cases of mistreatment and injuries is problematic in an industry as diverse and unregulated as the cosmetic industry. There are no legal requirements to report incidents, and operators who have caused an injury have an interest in it not being disclosed for fear of litigation and damage to reputation. In these circumstances, we have attempted to find the middle ground where respondents have been allowed to remain anonymous, and it is acknowledged that this has consequences for the reliability of the data. The purpose of the survey is to give an estimate of the extent of injuries, not absolute numbers.

2. Characteristics of the respondents

2.1 Number of responses by occupation

The table below lists the occupation of the respondents. Some of these respondents did not answer all components of the survey, or had some of their data removed during the cleaning of the data.

Occupation	Number of responses	
Dermatologist	103	Medical practitioners 165 38.4 %
Cosmetic Physician	38	
Plastic Surgeon	10	
General Practitioner	8	
Medical Practitioner - other	6	
Dermal Therapist	112	Non-medical practitioners 265 61.6 %
Beauty Therapist	105	
Enrolled Nurse	4	
Registered Nurse	22	
Other	11	
Did not specify	11	
Total	**430**	

Table 1 *Number of responses by occupation.*

2.2 Number of responses by State/Territory

Total responses	Responses	Population**	Responses per 100,000
NSW	137	7,381,100	1.86
VIC	127	5,713,000	2.22
QLD	89	4,638,100	1.92
WA	32	2,497,500	1.28
SA	21	1,667,500	1.26
TAS	12	512,900	2.53
ACT	5	381,700	1.31*
NT	2	237,800	0.84*
Total	**426**	**23,029,600**	**1.85**

* Low statistics

** Data from Australian Bureau of Statistics (March 2013)

Table 2 *Number of responses by State and Territory.*

The data shows that the responses to the survey are relatively evenly distributed across the country. The responses from the most populous states (NSW, VIC and QLD) are close to the national average.

In Tasmania IPL and laser licence holders were reached through the network of DHHS. This might explain why a higher response rate was achieved in Tasmania.

2.3 Estimate of survey response

To obtain an estimate of what portion of the industry we have studies in the survey, we compared the number of responses we received in the survey with the number of licensed operators in that particular state. This was done successfully for the data from Queensland and Tasmania. We were not able to correlate our data with the number of licensed operators in Western Australia, which is the other state that regulates lasers. The licences in Western Australia do not explicitly state if the licence is for cosmetic use or medical use, therefore we were not able to separate which licences relate to cosmetic use.

Comparison with data from QLD Health.

	From survey		Data from QLD Health	Percentage of licensees who have responded to survey
	Responses from QLD	Responses from QLD – laser operators only	Number of cosmetic laser use licensees	
Medical practitioners	34	19 55.9%	75	25.3%
Non-medical practitioners	55	18 32.7%	233	7.7%
Total	**89**	**37** **41.6%**	**308**	**9.7%**

Table 3 *Comparison with data from QLD Health.*

Comparison with data from TAS - DHHS

	From survey	Data from TAS-DHHS	Percentage of licensees who have responded to survey
	Responses from TAS (laser and IPL operators)	Number of cosmetic laser and IPL use licensees	
Medical practitioners	3	8	37.5%*
Non-medical practitioners	9	49	18.4%
Total	**12**	**57**	**21.1%**

*Note the low number of respondents makes this data unreliable.

Table 4 *Comparison with data from TAS – DHHS.*

There are a few potential problems with using the data from Queensland and Tasmania to estimate what portion of the industry we have reached:

- As we have got assistance from QLD Health and TAS-DHHS in reaching operators this has potentially skewed the data in that we might have reached more operators in Queensland and Tasmania than in other states. Using these numbers to estimate the total number of operators and cases of adverse outcomes, could mean that we underestimate the total number of injury cases in Australia. The number of responses by state and territory (Table 2) shows that we

have relatively evenly distributed responses compared to population, with the higher contribution by Tasmania reflected also in this data.

- There is a possibility that all operators are not appropriately licenced in TAS and QLD. The RHC working group believes that the number of unlicensed operators is low; however, it is possible that there are a small percentage of unlicensed operators.

- In Queensland Class 4 lasers are regulated for cosmetic purposes, but not Class 3B. This means that we are comparing data for Class 3B and 4 lasers in our survey with data for Class 4 lasers only from QLD Health. Most lasers used in the cosmetic industry are Class 4 lasers. An estimate by the RHC working group is that max 10% of lasers might be Class 3B. As these lasers are less powerful, they are less likely to cause injuries and would therefore form a minor part of the injury data.

Table 3 and 4 show that we have a total response rate of 10% in Queensland and 21% in Tasmania. As mentioned above we have reason to believe that the response rate in Tasmania is higher than the national average. The low statistics in the data for Tasmania also make the data unreliable. The response rate of 10% is assumed to be closer to the national average.

2.4 IPL and laser usage characteristics of respondents

Procedure	Number of practitioners performing procedure*	Estimated total number of procedures performed annually
Hair reduction	306	173,461-366,800
Skin rejuvenation	289	84,492-178,450
Treatment of vascular lesions	278	54,883-115,950
Treatment of pigmented lesions	277	70,080-148,050
Treatment of acne and other forms of scarring or striae	214	41,279-89,650
Resurfacing (traditional, fractional non-ablative, fractional ablative)	125	19,205-40,150
Tattoo removal	89	28,773-60,650

*using IPL, laser or both

Table 5 *Number of practitioners and an estimate of number of procedures performed annually.*

The estimate of total number of procedures was obtained by the respondent providing an estimate of the number of procedures in a given range. The lowest values have been added together and the highest values have been added together, hence the resulting estimate covers a large range.

Procedure	Share of provision by practitioner type (%)						Modality used (%)		
	Non-Medical			Medical			IPL	Laser	Both
Hair reduction	75.5			24.5			48.7	20.6	30.7
	IPL 52.8	Laser 18.2	Both 29.0	IPL 36.0	Laser 28.0	Both 36.0			
Skin rejuvenation	73.3			27.7			50.2	13.5	36.3
	IPL 60.8	Laser 7.7	Both 31.6	IPL 22.5	Laser 28.7	Both 48.7			
Treatment of vascular lesions	66.2			33.8			44.6	24.5	30.9
	IPL 56.5	Laser 17.4	Both 26.1	IPL 21.3	Laser 38.3	Both 40.4			
Treatment of pigmented lesions	68.9			31.1			50.4	14.8	34.7
	IPL 60.7	Laser 10.0	Both 29.3	IPL 27.9	Laser 25.6	Both 46.5			
Treatment of acne and other forms of scarring or striae	63.5			36.4			34.6	43.0	22.4
	IPL 51.5	Laser 22.8	Both 25.7	IPL 5.1	Laser 78.2	Both 16.7			
Resurfacing (traditional, fractional non-ablative, fractional ablative)	49.6			50.4			7.2	80.0	12.8
	IPL 14.5	Laser 66.1	Both 19.3	IPL 0	Laser 93.6	Both 6.3			
Tattoo removal	66.3			33.7			2.2	93.3	4.5
	IPL 3.4	Laser 91.5	Both 5.1	IPL 0	Laser 96.7	Both 3.3			

Table 6 *Share of provision by practitioner type and modality*

From the table above it is clear that lasers are used at a significantly higher rate by medical practitioners and IPLs are used at a higher rate by non-medical practitioners.

The apparent widespread use of IPLs to treat pigmented lesions (85%) is believed to be due to respondents interpreting 'treatment of pigmented lesions' as 'treatment of pigmentation'. IPLs are not suited for treatment of pigmented lesions and it is believed that most practitioners are aware of this. The share of practitioners that use IPLs for tattoo removal is close to 7 %. This is a concern as IPLs are not suited for tattoo removal.

2.5 Provision of contact details

A total of 178 respondents (out of 365) provided contact details (49%). The table below details whether the practitioner has provided contact details and what injury data they have provided. Practitioners that have reported on an injury they caused and on ones they have treated showed the highest willingness to provide contact details (65%). It is encouraging that practitioners who have caused an injury are willing to provide contact details.

	Practitioner has: Not treated injury Self-reported injury	Practitioner has: Treated injury Self-reported injury	Practitioner has: Treated injury Not self-reported injury	Practitioner has: Not treated injury Not self-reported injury
Total	27	52	151	135
Contact Details	13	34	71	60
% Contact Details	48.1	65.4	47.0	44.4

Table 7 *Provision of contact details.*

2.6 Support for regulation in the industry

It was not specifically asked in the survey whether individuals supported regulation, but many chose to in the 'additional comments' section. It cannot be deduced whether those who did not comment do or do not support regulation.

144 (39%) respondents offered their support for regulation in the 'additional comments' sections. An additional 33, without going so far as suggesting regulation, noted the importance of training in preventing injuries. Eight respondents raised doctors checking lesions before treatment as something that they do, which they believed was best practice.

Recommended regulation ranged along a variety of options. Some suggested minimum training requirements, other medical practitioner supervision, limiting use to medical practitioners, licensing standards, and the need to have clients' lesions checked by a medical practitioner before treatment.

Throughout the professions there was solid support for regulation. By occupation, there is not a significant amount of variation.

It should be remembered, as noted in Section 1.3, that operators who are concerned about injuries and mistreatment are more likely to respond to the survey. Therefore the results are likely to be somewhat skewed.

Occupation*	Support for regulation (fraction)	Support for regulation (percentage)
Beauty Therapist	31/92	34
Dermal Therapist	44/100	44
Cosmetic Physician	12/28	43
Dermatologist	31/85	36
EN & RN	10/22	45
Not specified/other	12/20	60
Total	**144/365**	**39**

* GPs, plastic surgeons and other medical practitioners were excluded as occupations due to low numbers.

Table 8 *Support for regulation by occupation.*

3. Injury data

3.1 Comparison of number of injuries with total number of procedures being performed

The respondents were asked to specify the extent of the adverse outcome. The following adverse outcomes were listed, and have been divided into minor and severe outcomes:

Blistering (mild)	minor adverse outcome
Blistering (moderate)	minor adverse outcome
Blistering (severe)	severe adverse outcome
Burn (minor)	minor adverse outcome
Burn (severe)	severe adverse outcome
Persistent/permanent pigment alteration	severe adverse outcome
Infection	minor adverse outcome
Scarring	severe adverse outcome
Eye injury	severe adverse outcome
Other (please specify)	

A number of respondents specified 'temporary pigment alteration' in the other category. This has been listed separately in the tables below. There was only one case of an eye injury reported in the survey.

	Number of severe injuries (treated and self-reported)		Number of total injuries (treated and self-reported)		Estimated total number of procedures performed annually by participants in the survey*
Procedure	**N**	**%**	**N**	**%**	
Hair Reduction	107	0.040%	174	0.064%	270,130
Skin rejuvenation	70	0.053%	103	0.078%	131,470
Treatment of vascular lesions	32	0.037%	49	0.057%	85,410
Treatment of pigmented lesions	74	0.068%	101	0.093%	109,060
Treatment of acne, scarring or striae	9	0.014%	10	0.015%	65,460
Tattoo removal	29	0.065%	37	0.083%	44,710
Resurfacing	22	0.074%	33	0.11%	29,680
Total number of injuries**	**268**		**416**		

*The midpoint from the range given in Table 5 has been used.

** Several respondents have stated that the injury was caused when multiple procedures were being performed. Therefore the total number of injuries is less than the sum of the injuries in this table.

Table 9 *Comparison of injuries with total number of procedures being performed.*

The data in table 9 has been produced to investigate whether there is a high prevalence of injuries associated with specific procedures. The data indicates that there are more injuries associated with resurfacing and, to a lesser extent, with treatment of pigmented lesions. Hair reduction is the most common procedure and the injuries seen are close to the average for all procedures.

The data in this table gives an indication of the extent of injuries associated with cosmetic procedures. Obtaining accurate numbers of the total number of the treatments performed is problematic. This data relies on estimates of the number of procedures that the participants in the survey provide. As mentioned in section 2.3 we estimate that we have data from approximately 10% of the cosmetic industry in our survey.

3.2 Number and severity of injuries by procedure

	Treated - severe		Treated - minor		Self-reported - Severe		Self-reported - Minor	
	N	%	N	%	N	%	N	%
Hair Reduction	99	42.5	39	51.3	8	22.9	28	38.9
Skin rejuvenation	64	27.5	21	27.6	6	17.1	12	16.7
Treatment of vascular lesions	24	10.3	5	6.6	8	22.9	12	16.7
Treatment of pigmented lesions	64	27.5	13	17.1	10	28.6	14	19.4
Treatment of acne, scarring or striae	8	3.4	1	1.3	1	2.9	0	0.0
Tattoo removal	24	10.3	2	2.6	5	14.3	6	8.3
Resurfacing	18	7.7	4	5.3	4	11.4	7	9.7
Total adverse outcomes*	**233**		**76**		**35**		**72**	

* NB. Some injuries were related to more than one procedure being conducted together. Therefore the total number of adverse outcomes is not the sum of the injuries by procedure.

Table 10 *Number and severity of injuries by procedure.*

3.3 Characteristics of injury data

The options listed below were given to describe the cause of the adverse incident. They have been grouped into three categories describing the cause of the injury: training, equipment and client.

An untrained operator	training
Insufficient operator training	training
Inappropriate use of the laser/IPL (e.g. incorrect device or setting)	training
Malfunctioning equipment	equipment
Not recognised equipment (not TGA approved or certified)	equipment
Non-compliance by the client	client
Contraindications that may make skin more sensitive to light therapies were not disclosed by the patient	client
Unsure	
Other (please specify)	

Tables 11 and 12 list details of the adverse outcomes. In the self-reported adverse outcomes the cause of injury is attributed to a larger extent to the client (almost 40%) as compared with around 10% for adverse outcomes reported by the practitioner treating the injury. This highlights the subjectivity in attributing the cause of an adverse outcome. In the same way training is identified as a cause of injury for around 50% of the self-reported injuries as compared with around 90% for adverse outcomes that have been reported by someone who did not cause the injury. The percentage attributed to equipment is approximately constant.

The average medical cost per severe adverse outcome is $1,210 (both treated and self-reported). In 40% of cases there was a loss of working time associated with the injury (reported by the treating practitioner).

Severe adverse outcomes

		Severe adverse outcomes				
Self-reported by practitioner completing survey	Number	35				
	Adverse Outcome (%)	Eye injury	Severe blistering	Severe burn	Perm pigm alt	Scarring
		0%	9%	6%	83%	14%
	Share requiring medical management	51% (0 not known)				
	Total medical cost	$5,008-$10,284 (2 not known)				
	Average medical cost/adverse outcome	$462 (N=16)				
	Share of outcomes that resulted in a loss of working time	9% (9% not known)				
	Loss of working time (working days)	Total: 62 Average: 31 Median: Not meaningful as only based on 2 cases N=2 (1 not known)				
	Cause of injury	Training	Equipment	Patient	Unsure	
		54%	9%	37%	20%	
Treated by practitioner completing survey	Number	233				
	Adverse Outcome (%)	Eye injury	Severe blistering	Severe burn	Perm pigm alt	Scarring
		0.4%	19%	20%	79%	41%
	Share requiring medical management	65% (11% not known)				
	Total medical cost	$120,207-$208,077+ (28 not known)				
	Average medical cost/adverse outcome	$1,305 (N=124)				
	Share of outcomes that resulted in a loss of working time	39% (28% not known)				
	Loss of working time (working days)	Total: 1184+* Average: 14 Median: 5 days N=85 (7 not known)				
	Cause of injury	Training	Equipment	Patient	Unsure	
		94%	7%	8%	6%	

*Two adverse outcomes have been reported with a loss of working time of more than 1 year each. This accounts for 480 working days (240 + 240).

Table 11 *Severe adverse outcomes.*

925 **Minor adverse outcomes**

		Minor adverse outcomes				
Self-reported by practitioner completing survey	Number	72				
	Adverse Outcome (%)	Mild blistering	Moderate blistering	Minor burn	Temp pigm alt	Infection
		46%	7%	29%	19%	13%
	Share requiring medical management	35% (1% not known)				
	Total medical cost	$2,111-8,576 (1 not known)				
	Average medical cost/adverse outcome	$200 (N=24)				
	Share of outcomes that resulted in a loss of working time	10% (8% not known)				
	Loss of working time (working days)	Total: 28 Average: 4.0 Median: 2 N=7 (0 not known)				
	Cause of injury	Training	Equipment	Client	Unsure	
		47%	4%	39%	13%	
Treated by practitioner completing survey	Number	76				
	Adverse Outcome (%)	Mild blistering	Moderate blistering	Minor burn	Temp pigm alt	Infection
		34%	28%	47%	8%	3%
	Share requiring medical management	30% (13% not known)				
	Total medical cost	$4,605-$11,981 (4 not known)				
	Average medical cost/adverse outcome	$408 (N=19)				
	Share of outcomes that resulted in a loss of working time	18% (25% not known)				
	Loss of working time (working days)	Total: 60 Average: 5.4 Median: 5 days N=11 (2 not known)				
	Cause of injury	Training	Equipment	Client	Unsure	
		80%	7%	11%	18%	

926 ***Table 12*** *Minor adverse outcomes.*

927

3.4 Occupation of those who self-reported an injury

Occupation	Number reporting an injury**	Share of incidences (%)	Share of survey respondents (%)
Beauty Therapist	20	24.7	26.1
Dermal Therapist	16	19.8	28.6
Nurse	9	11.1	6.4
Cosmetic Physician	17	21.0	8.4
Dermatologist	9	11.1	20.2
Plastic Surgeon	5	6.2*	1.7
Medical Practitioner – Other	1	1.2*	1.7
Other/Not specified	3	3.7*	5.6
General Practitioner	1	1.2*	1.4
Total	81		

* Statistics too low.

** Some respondents reported more than one injury.

Table 13 *Occupation of those who reported an injury they caused.*

While not a terribly robust measure, the above indicates that the only cohort to have an overrepresentation of self-reported injuries were cosmetic physicians and, to a lesser degree, nurses. The results indicate that dermal therapists and dermatologists have a lower share of self-reported injuries.

3.5 Self-reported injuries by states and territories

State	Number of respondents	Total number of respondents with at least one self-reported injury	Total percentage of state respondents with at least one self-reported injury
NSW	137	30	21.9%
VIC	127	21	16.5%
QLD	89	10	11.2%
WA	32	10	31.3%
SA	21	4	19.0%
TAS	13	5	*
ACT	5	0	*
NT	2	1	*

*Statistics too low.

Table 14 Number and percentage of respondents with self-reported injuries by state and territory.

The data does not factor in whether respondents listed more than one incident in the last year. The states where lasers (and IPLs in Tasmania) used for cosmetic purposes are regulated are shaded. It cannot be concluded from these results that states where regulation of lasers is in place exhibit lower rate of injuries. The data suggest that Queensland does have a lower rate or self-reported injury responses compared to other states or territories. However, Western Australia appears to have a higher rate. Due to the low statistics it is difficult to draw any conclusions.

4. Skin cancer diagnosis data

The survey attempted to provide an estimate of the number of cases where a pigmented lesion was incorrectly treated by an IPL or laser, and this resulted in delayed or missed diagnosis of skin cancer.

This section of the survey was completed by medical practitioners only. The following question was posed:

In the last year, have you encountered cases where the diagnosis of a non-melanoma skin cancer or melanoma has been delayed or missed because a pigmented lesion was inadvertently treated using an IPL or laser?

Number of medical practitioners who replied	**142**	
	No	Yes
N	111	31
%	78%	22%

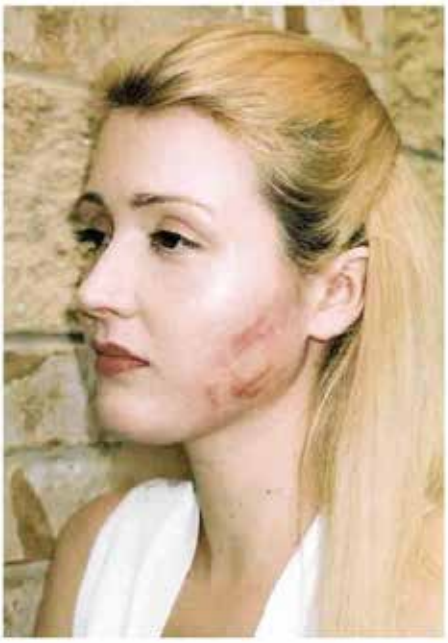
Table 15 *Treatment of pigmented lesions.*

Total number of cases where diagnosis of skin cancer was delayed or missed	**62**					
By type of skin cancer	**Melanoma**			**Non-Melanoma**		
N	22			40		
%	35%			65%		
Type of practitioner that performed the treatment	Medical	Non-Medical	Unknown	Medical	Non-Medical	Unknown
N	7	13	2	14	24	2
%	32%	59%	9%	35%	60%	5%

Table 16 Skin cancer diagnosis data.

There were 62 cases where diagnosis of skin cancer was delayed or missed due to a pigmented lesion being inadvertently treated. A number of practitioners listed several cases. Out of these there were 22 cases where diagnosis of a melanoma was missed or delayed. Melanoma is the most dangerous form of skin cancer with the highest mortality rate and early detection is critical. Five year survival for people diagnosed with melanoma is 91%, rising to 99% if the melanoma is detected before it has spread (Cancer Council Australia). In Australia skin cancers account for around 80% of all newly diagnosed cancers and the incidence of skin cancer is one of the highest in the world.

5. **Photos of injuries caused by IPL and lasers** – some examples.



Burns at 3 days (above) followed by hypertrophic and atrophic scarring at 3 months post silicone gel sheet therapy (Operator Error)

Example 1 *Burns from IPL or laser treatment.**

Example 2 *Burns from IPL treatment.*

Post IPL blistering and subsequent permanent scarring (Operator Error)

Example 3 *Permanent scarring from IPL treatment.**

Example 4 *Burns following hair removal with IPL.*

*****Photos provided by Godfrey Towns.

Appendix C – Status Quo

Status Quo

Health costs

Severe outcomes

Medical costs

Self reported

average cost/outcome	$462		
Number of adverse outcomes	35		
Share requiring medical management	0.51		
		range	
Total medical cost	**$8,247**	**$5,008-$10,284**	

Treated

average cost/outcome	$1,305		
Number of adverse outcomes	233		
Share requiring medical management	0.65		
		range	
Total medical cost	**$197,642**	**$120,207-$208,077**	
Total cost (survey)	**$205,889**	**$125,215-$218,361**	
Total cost in society	**$2,058,890**	**$1,252,150-$2,183,610**	

Loss of working time

Self reported

		range	
		<=1day	**>1day**
average lost worktime (days)	31		
Number of adverse outcomes	35		
Share resulted in lost worktime	0.09		
Total lost worktime (only two cases)	**97.7**		

Treated

		range	
		<=1day	**>1day**
average lost worktime (days)	14	1	15
Number of adverse outcomes	233	233	233
Share resulted in lost worktime	0.39	0.39	0.39
Total lost worktime	**1272**	**91**	**1363**
Total lost work time (survey)	1370	91	1461
Total lost work time in society	**13698**	**910**	**14607**
Person years	57.1	3.8	60.9
Cost/lost day	$303	$303	$303
Total cost for society	**$4,150,585**	**$275,730**	**$4,425,921**

Minor outcomes

Medical costs

Self reported

average cost/outcome	$200		
Number of adverse outcomes	72		
Share requiring medical management	0.35		
		range	
Total medical cost	**$5,040**	**$2,111-$8,576**	

Treated

average cost/outcome	$408		
Number of adverse outcomes	76		
Share requiring medical management	0.3		
		range	
Total medical cost	**$9,302**	**$4,605-$11,981**	
Total cost (survey)	$14,342	$6,716-$20,557	
Total cost in society	**$143,424**	**$67,160-$205,570**	

Loss of working time

Self reported

		range		
		<=1day	**>1day**	
average lost worktime (days)	4	0	4	
Number of adverse outcomes	72	72	72	
Share resulted in lost worktime	0.1	0.1	0.1	
Total lost worktime	**28.8**	**0**	**28.8**	

Treated

average lost worktime (days)	5.4	0	5.4	
Number of adverse outcomes	76	76	76	
Share resulted in lost worktime	0.18	0.18	0.18	
Total lost worktime	**74**	**0**	**74**	
Total lost work time (survey)	103	0	103	
Total lost work time in society	**1027**	**0**	**1027**	
Person years	4.3	0.0	4.3	
Cost/lost day	$303	$303	$303	
Total cost for society	**$311,096**	**$0**	**$311,096**	

Total severe and minor

Total cost in society	**range**
$2,202,314	**$1,319,310-$2,389,180**

	<=1day	**>1day**
Total lost work time in society	910	15634
Person years	3.8	65.1
Total cost in society	**$275,730**	**$4,737,017**

Appendix D – Options Compared

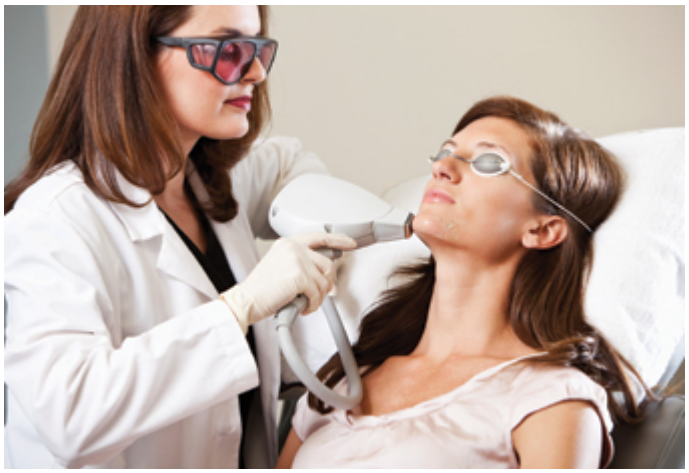
Status Quo			**Option 1**	(Educational Awareness)			**Option 2**	(Self regulation)			**Option 3**	(Regulatory option)				
Cost of consumer awareness campaigns																
$0				$15 to $20 million			N/A				N/A					
Cost of additional training									NPV	NPV			NPV	NPV		
$0				$0			$220,000 - $472,000		**$1,649,708.35**	**$3,539,374.29**	$1,055,250 - $2,261,250		**$7,912,976**	**$16,956,377**		
Licencing (estimates based on Tas and QLD)													NPV			
TAS $324x57 = $18468/yr	NPV =	**$138,725.48**		N/A			N/A				2100x$300/yr = $630,000		**$4,724,164.83**			
QLD $140x453 = $63420/yr	NPV =	**$476,165.82**									4500x$300/yr = $1,350,000		**$10,123,210.36**			
Cost to consumers																
included in business costs				included in business costs			included in business costs				included in business costs					
Cost to regulatory agency																
recovered through licensing (TAS,QLD)				N/A			N/A				recovered through licencing					
Costs legislative changes																
One off cost and are not generally costed in RIS (TAS,QLD)				N/A			N/A				N/A					
Training				estmate 30% uptake (630-1350 operators)			take average turnover 15%						beauty therapists (numbers)		**Training Costs**	
2100-4500 operators				at $3500 for the course			315-675 operators				Cat 1 (hair removal)		15%		$2,500	
take average turnover 15%				$2,205,000 - $4,725,000			at $3500 for the course				Cat 2 (skin therapies)		85%		$3,500	
315-675 operators				take average turnover 15%			$1,100,000 - $2,360,000				10-20% turnover/yr		Cat 1	Cat 2	Total	NPV
							depends on participation numbers				take average turnover 15%		$118,125	$937,125	**$1,055,250**	**$7,912,976**
							take 20% participation				315-675 operators		$253,125	$2,008,125	**$2,261,250**	**$16,956,377**
				$330,000 - $640,000			**$220,000 - $472,000**									
			NPV=	**$2,474,563**	**$4,799,152**		NPV=	**$1,649,708**	**$3,539,374**							
			Benefits				Benefits				Benefits					
Medical costs		Work time lost	Medical		Work time lost		Medical		Work time lost		Medical		Work time lost			
Severe injuries		Severe injuries	avoided		avoided		avoided		avoided		avoided		avoided			
$1,252,150 to $2,183,610		910 to 14607 days	10% decrease	NPV	10% decrease	NPV	10% decrease	NPV	10% decrease	NPV	50% decrease	NPV	50% decrease	NPV		
Minor injuries		Minor injuries	$132,000	**$989,825**	$27,500	**$206,214**	$132,000	**$989,825**	$27,500	**$206,214**	$660,000	**$4,949,125**	$138,000	**$1,034,817**		
$67,160 to $205,570		1027 days	$239,000	**$1,792,183**	$474,000	**$3,554,372**	$239,000	**$1,792,183**	$474,000	**$3,554,372**	$1,195,000	**$8,960,916**	$2,368,500	**$17,760,610**		
Annual Costs		Annual Costs (at $303/day)	30% decrease		30% decrease		20% decrease		20% decrease		90% decrease		90% decrease			
$1,319,310 to $2,389,180		**$275,730 to $4,737,017**	$396,000	**$2,969,475**	$82,800	**$620,890**	$264,000	**$1,979,650**	$55,200	**$413,927**	$1,188,000	**$8,908,425**	$248,400	**$1,862,671**		
			$717,000	**$5,376,549**	$1,421,100	**$10,656,366**	$478,000	**$3,584,366**	$947,400	**$7,104,244**	$2,151,000	**$16,129,648**	$4,263,300	**$31,969,098**		

Laser and IPL hair removal: are they safe?

We expose a number of untrained operators aiming lasers at your body.

Choice, May 2013

01. Introduction



Permanent hair reduction is becoming increasingly popular, and hair removal businesses are cropping up as fast as the hairs themselves. We take a look to see if it's all it's cracked up to be.

On this page we look at:

- How it works
- Is it permanent?

Through this investigation into permanent hair reduction practices in Australia, CHOICE has found several examples of customers paying for ineffective treatments, or even worse, being injured.

- Laser Danger CHOICE spoke to a range of experts, including dermatologists, and medical professionals who have highlighted the dangers involved in getting laser and IPL treatments, especially in an unregulated environment.
- The CHOICE shadow shop We also sent a shadow shopper into a mix of beauty salons and walk-in clinics, and discovered that a number of laser and IPL operators are failing to give accurate advice, ask necessary questions, and provide adequate information about the training of staff.
- What to look out for If you're considering laser or IPL treatments, CHOICE has compiled a list of tips to help you make an informed decision.

The marketing hype will tell you that with a few sessions of laser or intense pulsed light (IPL) hair reduction, and some slight discomfort, you can be hair free forever. To anyone who has battled with unwanted facial or body hair this sounds like the perfect solution.

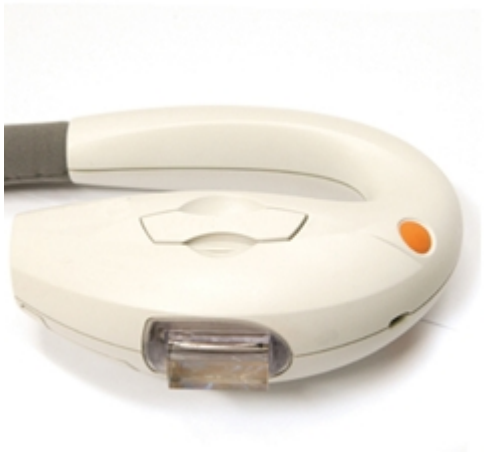
However, with the exceptions of Queensland, Tasmania and WA the laser industry is unregulated, and powerful medical lasers and IPLs are accessible to untrained and inexperienced personnel. Even in the states with some legislative controls, clinical application training isn't covered.

How it works

Lasers and IPL (intense pulsed light) devices, (which are not technically lasers but work on a similar principal), can be used for hair reduction and skin treatments such as removing spider veins, improving skin tone and to remove tattoos.

- Permanent hair reduction involves the use of either a single wavelength of light (laser) or a flash of light containing hundreds of wavelengths (IPL or broadband light BBL).
- Melanin within the hair follicles is targeted, heating and damaging the follicles in an active growth cycle.
- Only hairs that have colour can be treated, so white and grey hairs won't respond.
- Success of the treatment depends on your colouring, with laser generally working best on fair skin and dark hair.
- Fairer skin and red hair will respond to a lesser degree and those with darker skin can be treated, but only with a great deal of care.

All the experts CHOICE spoke to agree that laser or IPL treatment, in the hands of an experienced and trained operator can be very effective. Melbourne dermatologist Dr Philip Bekhor says its the best way to remove unwanted hair, as long as you're a "suitable candidate".



Is it permanent?

Many adverts claim that laser or IPL treatments can leave you permanently hair free. Sydney dermatologist Dr Phillip Artemi, says many operators have been quite loose with their definition of the word "permanent" in their advertising.

He says up to 20% of hair will continue to grow (albeit in a finer and slower way), and many hair follicles will recover from the laser injury over time.

Dr Artemi says a better term for the procedures is "permanent hair reduction".

02. Laser danger

Melbourne dermatologist Dr Philip Bekhor says he is seeing a steady increase in patients presenting with complications caused by inexperienced laser and IPL operators, from hyper and hypo pigmentation to severe burns and scarring.

The NSW Statewide Burn Injury Service recorded 6 patients who required treatment for serious burns in the last year from Laser and IPL and Beth Wilson, Health Commissioner of Victoria says her office has also received complaints from the members of the public about inexperienced operators.

Dr Sharron Phillipson also sees about one patient a month who has had a bad experience elsewhere. While Phillipson is quick to point out that lasers can be safe and effective she says: "It is the uncontrolled use in the cosmetic area which is the cause for concern."

Another concern is that untrained operators may be clueless if things go wrong, and in some instances compound the problem by dispensing misguided advice.

In Victoria the Health Commissioner investigated an incident where a woman had IPL treatment on her legs at a salon which resulted in painful dark purple stripes. When she went back the next day in more pain she was told 'not to worry as it will go away in a couple of months' it was then suggested she visit a solarium or sit in the sun to even up her skin tone. A GP later diagnosed the woman with first degree burns and depigmentation which is not reversible.

Dr Bekhor says he has had a mother bring her child to him with complications after a beautician tried to remove a birthmark with an IPL device. He says many operators buy the machines initially for hair removal but then start trying other treatments.

Where's the regulation?

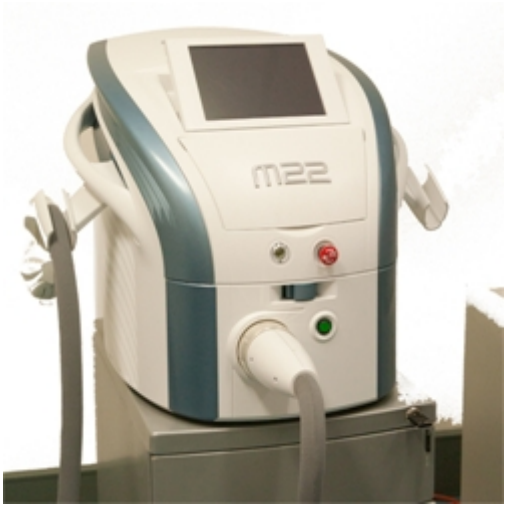
- There are no Commonwealth regulations on the use of laser and IPL. Currently Tasmania, WA and Queensland regulate the industry in some way for lasers, however none have moved to regulate IPL.
- The Therapeutic Goods Administration (TGA) regulates the importation of both lasers and IPLs when they are used for "therapeutic purposes". However hair removal isn't considered a therapeutic use, so a machine bought for this purpose doesn't have to be registered.
- The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) says it will review the use of IPLs and lasers for cosmetic purposes, and look at the case for any regulatory action.

The experts CHOICE spoke to, from doctors, dermatologists and the Cosmetic Physicians Society of Australasia, believe that the reported cases are just the tip of the iceberg and that many incidents remain unreported due to embarrassment and simply not knowing where to complain.

Associate professor Lee Collins, director of the medical physics department at Westmead Hospital in NSW, says that most reported incidents come from medical personnel who have a legal requirement to report accidents, however there is no legal requirement for people to report laser / IPL accidents if they are untrained.

However as the industry continues to grow both Collins and Phillipson say there will be more accidents, more often.

The rise and rise of hair removal devices



In the past, laser and IPL hair removal was primarily the domain of dermatologists and doctors and was expensive. These days, it's likely you could be offered a similar treatment in your local shopping centre for significantly less. So what's changed?

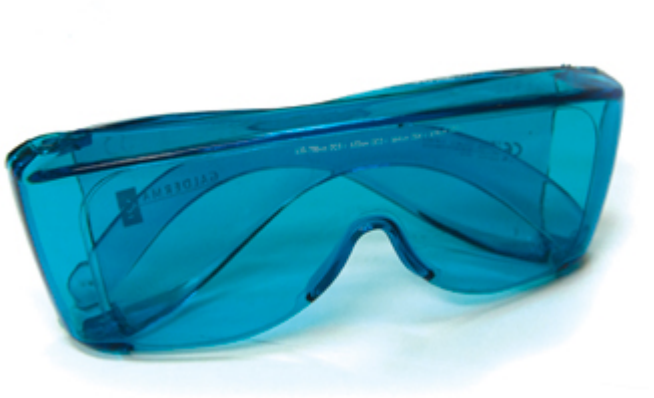
The main reason is the cost of the equipment. In the past these devices were extremely pricey, one doctor told CHOICE she paid $300,000 for one machine 12 years ago.

Now the market has been flooded with a wide variety of devices which are relatively cheap to buy.

A search on Ebay reveals pages of new and second hand machines from as little as $3000, and in the states with no regulation anyone can buy a machine and set up shop.

03. The CHOICE shadow shop

CHOICE sent consumer Kerry out in Sydney to make enquiries about having permanent hair reduction treatment on her legs at a mix of beauty salons and walk in clinics.



Kerry, who has fair skin and a mix of fine brown and blonde hairs, was assessed by Dr Sharron Phillipson, who specialises in permanent hair reduction, before visiting the salons.

Phillipson says that while Kerry is suitable for treatment, her fairer hairs may not respond as well. Kerry also has a slight tan which is not ideal prior to treatment.

Phillipson said it's important that all operators ask if she has any medical conditions or was on any medication as well as checking to see if she had a tan.

The first salon went into detail about the treatment but when asked about training, the operators were trained by the machine manufacturer only. They were also keen to get her to pre-pay for 6 treatments for a small discount, although earlier they said she'd only need 5 treatments in total.

- The advice on the number of treatments Kerry would need ranged from just 5 at one salon to 10 at a clinic.
- On staff training the responses ranged from training by the manufacturer to none but "it's okay, we've been doing this for years".
- Most places used plenty of technical jargon but struggled when questioned further.
- One clinic insisted all the staff had "qualifications" but couldn't provide details.
- Another said their team was trained in the use of "Fraxel" which is a device used to treat skin, but isn't used for hair reduction.
- One clinic told Kerry that the reason they use an IPL machine is because "lasers can burn you".
- None of the establishments Kerry visited asked about medical conditions, if she was taking any medication or if she had been tanning.

User experiences with laser and IPL hair removal

The Good

"I had dark facial hair on my upper lip which I was very self-conscious about. I had a number of laser treatments and most of the hair is gone now." – Liz

"I had two sessions of laser hair removal. I went to a professional, reputable company….even with two sessions there was a significant permanent difference." - Lyn

"I suffered from shaving rash on my neck. I had laser hair removal done through a dermatologist with trained nurses operating the laser. After one treatment I had a noticeable improvement. After 4 treatments I no longer have a shaving rash or a sore neck from infected hairs if I don't shave. I've been very happy with the results" – Craig.

The Bad

"The beautician was skipping shots on me and charging the full price, it made me look like a zebra and it all grew back eventually anyway". – Cheryl

"I had about 10 sessions; it slightly reduced the hair initially, but now 12 months later it's back as it used to be". – Katie

"It was very expensive and while it seemed to be doing a good job, as soon as I stopped having sessions the hair grew back." - Evelyne

The Ugly

"I had IPL at a beautician and the pain was unbelievable, it felt like a blow torch. She told me 'It's fine' and

encouraged me to keep going. Later I went to the doctor in agony; I was told I had severe burns. Six years later I still have terrible scars." Deborah.

"I tried IPL at a beauty salon and I was left with blistering burns." – Chloe

"I regularly see patients that have adverse outcomes with laser and IPL treatments. Sometimes the damage is temporary, but two of my recent patients suffered deep skin burns which has left them with permanent scarring on the face." Dr Philip Bekhor, Dermatologist.

04. What to look out for

While the industry remains largely unregulated the decision about who to use still rests with the consumer. Here are some tips to help you make a decision:

Ask questions what kind of training and qualifications do the staff have? Who will be doing the treatment? The ideal clinic will have medically trained staff, and a Doctor, Cosmetic surgeon or Dermatologist overseeing the treatments.

Consultation and medication: The operator should conduct a full consultation assessing your skin type and hair colour. They should also check your medical history and if you are on any medication that may affect the treatment and outcome.

Don't fall for the hard sell: Don't be seduced by sales offers and pre-pay options. While it can be an expensive treatment, you are better off in the hands of an experienced operator who will get the best results rather than pre-paying for a treatment that mightn't work for you.

Walk away if you feel uncomfortable or they can't answer your questions. Also if you've had more than four treatments with little result it might be time to go elsewhere.

Tattoo removal

More and more tattoo removers are setting up shop - and if you're not careful, you might get burned.

Choice, October 2013

01. Tattoo removal

About one quarter of Australians under age 30 have a tattoo, and more than a quarter of that group are looking to have it removed. But who's doing the removing? The tool of choice these days is a laser, which can and has caused burns and permanent scars on tattoo removal patients. But that doesn't mean you need to have any medical training to use one. CHOICE talked to experienced laser removers and dermatologists to find out how to navigate the fast-growing - and largely unregulated - tattoo removal industry.

The right skills

Some removers offer medical-sounding assurances such as "Certified Laser Practitioner" or "accredited clinician", which generally means they took a course given by the laser maker - often a prerequisite for getting liability cover. But that doesn't mean they're any good at removing tattoos. Hilary Quinn, proprietor of Melbourne Tattoo Removal in the suburb of Caulfield, has been in the business for five years and says she's seen more than a few scarred patients who have suffered at the hands of an unskilled remover."I took a laser safety course, but that's only about using lasers safely, not tattoo removal," Quinn said. "That's a skill you acquire over time, and you need to approach it like an apprentice and build up your technique under the guidance of an experienced remover. The industry has really boomed, especially in the last six months or so, and unskilled practitioners far outweigh skilled ones."

Dr Philip Bekhor, Director of the Laser Unit at Melbourne's Royal Children's Hospital, backs up Quinn's assessment. "In Victoria your local butcher could sideline in laser tattoo removal, and many removers scar up a lot of patients before they develop any real skill. In reality the process is extremely slow, not every colour responds well, and it can be painful. It's an invasive procedure with the capacity for injury."

The right machine

Both Bekhor and Quinn say widespread use of cheaper knock-off versions of the industry standard Q-switched laser - or worse, the use of IPL lasers - are a main cause of injury and unsuccessful tattoo removal. It's no coincidence that proper Q-switched machines cost about $150,000, while IPL lasers go for between $10,000 and $15,000. The lower cost of getting into the business in recent years is one reason for the sharp increase in the number of tattoo removers.

"The problem is that the IPL lasers function in milliseconds instead of nanoseconds, and the wavelength is too broad," Bekhor points out. "They're marketed as an all-purpose machine, including tattoo removal, but shouldn't be used for that purpose. They often cause distorting of the tattoo and horrific burns and scars."

Quinn makes the same point. "Every second beautician seems to be offering tattoo removal with an IPL laser these days. It should not be used for that. It shoots a block of light of about two by six centimetres rather than the five to eight millimetre pinpricks of Q-switched lasers. It's like trying to crack an egg with a machine gun."

02. How much?

Removal techniques have come a long way since the days of skin grafting, skin removal, or the use of infra-red and other non-medical lasers. Best practice these days dictates that unwanted tattoos be gradually broken apart through the use of Q-switched lasers set to specific wavelengths (depending on skin type and the colour and location of the tattoo).

The lasers are used in short bursts to break up the ink; then the immune system goes to work and gets rid of the dispersed particles over the course of many months and treatments (up to 15 treatments, six to eight weeks apart, for multicoloured tattoos). How many treatments you'll need varies according to how well your immune system clears the pigment after treatments, the location and colour of the tattoo, and your skin type. It can be a costly undertaking, especially if your tattoo is large, densely inked, and has a lot of colours – probably a lot more expensive than getting the tattoo in the first place.

Tattoos made of up black inks only are much easier to remove that ones with colour, and some removers won't take on clients with coloured tattoos. Green is the toughest colour to remove. Taking average prices in Sydney and Melbourne as a guideline, you would pay about $4500 to get a 10 x 10cm multi-coloured tattoo removed

and $19,500 to get rid of a 30 x 40cm multi-coloured tattoo. And it may cost more than you're inititally led to believe.

One of the main worries for consumers seeking tattoo removal is deliberate underestimating of the number of treatments required. It will be too late to turn back if the promised number of sessions pass and your tattoo is still half there. It pays to think ahead, says Melbourne-based remover Hilary Quinn. "Very fine shading that you can see through can be removed in just one to three treatments as it's the least amount of ink a tattooist can put down. The same applies to very fine lines. Thicker lines and block ink take much longer to remove. It can save a lot of heartache to select an easily removable tattoo if it's your first one. These are the ones that are most often regretted."

The cream question

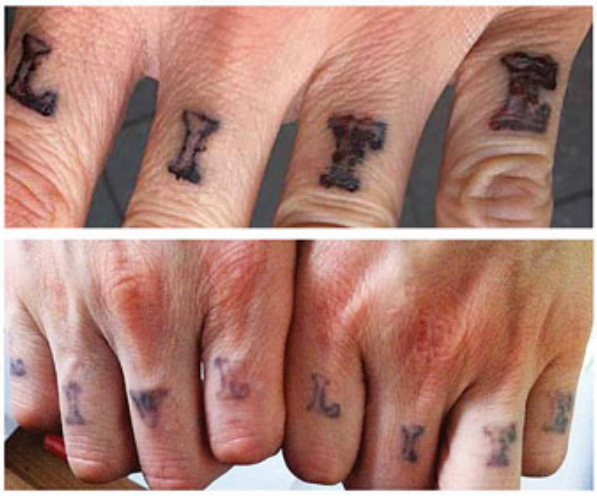
Creams and other topical treatments promising tattoo removal can be tempting given the cost and commitment of going under the laser. Such products are also widely advertised on international websites, which means they can be purchased without passing through local Therapeutic Goods Administration regulation. Whatever their origin, it would be more accurate to call them tattoo-fading treatments since, according to dermatologists, they can only lighten a tattoo at best with repeated use.

And the better they lighten, the more you should worry. Products that contain ingredients such as trichloroacetic acid– arguably the ingredients they would need to contain to have any reasonable efficacy – can burn and inflame the skin or pose cancer risks. As one dermatologist at the well-respected Mayo Clinic in the US puts it, "if you're interested in tattoo removal, don't attempt it on your own".

03. Tattoo regret: the stats

When you consider the following statistics, it's no wonder business is booming for start-up tattoo removers – there's no shortage of potential customers!

- 22% of Australian men and 29% of women aged 20 to 29 have at least one tattoo.[1]
- 34% of Australians who have a tattoo regret getting it, and one in seven of this group are considering removal.[2]
- 22% of US students had a tattoo at the time of a 2007 US study, and 28% of them regretted getting it within a year. Half the study subjects ended up getting their tattoos removed as adults.[3]
- 47% of tattoos require up to 10 sessions to successfully remove with a Q-switched laser.[4]
- 26% require more than 15 sessions.[4]



Ada's inked fingers after undergoing one session (top) and after five (bottom).

- Your response to the Q-switched laser removal process will be reduced if you smoke, have tattoo colours other than black and red, have a tattoo larger than 30 square centimetres, or have a tattoo on your feet or legs more than three years old.[4]

Sources:

[1] Australian National Health and Medical Research Council study published in 2012.

[2] Sydney-based McCrindle Research study published in 2013.

[3] *Journal of Adolescent Health* (US).

[4] *Journal of the American Medical Association*.

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Horror laser therapy burns prompt regulation calls

SOPHIE COUSINS

HORRIFIC images of burns on a woman's chest from laser therapy have reignited calls for the industry to be regulated.

The injuries, sustained at a beauty salon in Sydney, have experts demanding the introduction of national regulations on the use of IPL and lasers for cosmetic treatments.

Dr Sharron Phillipson, immediate past president of the Australasian Society of Cosmetic Medicine, was the cosmetic physician the patient was referred to for management of the burns.

"It was inappropriate treatment, in a dangerous area," Dr Phillipson, director of the Elizabeth Medical Centre in North Sydney, said.

"The person doing it was young and didn't recognise it was burning and was not capable of managing the problem when it occurred."

Currently anyone can buy and operate a laser for cosmetic use in most parts of Australia, with no training or standards in place. Operators have been charging about $65 per five-minute treatment.

Dr Phillipson, along with medical radiation safety expert Associate Professor Lee Collins from Westmead Hospital, said in a letter to *Australian Doctor* the industry needed to be regulated.

"The laser industry is currently totally unregulated and strong lasers are put in the hands of untrained and inexperienced personnel," they wrote.

"Without some form of regulation, we will be seeing more young women being burnt by lasers in inexperienced hands."

Professor Collins said while there were a number of responsible cosmetic laser users, there were a significant number who were not.

It is understood the Australian Radiation Protection and Nuclear Safety Agency — which has been given the task of regulating the industry — has drafted a document that would require some level of training and supervision of IPL or laser therapy.

The Cosmetic Physicians Society of Australasia have also renewed their calls for national regulation to help improve patient safety.

"Anyone can now buy an IPL or laser device and set themselves up without requiring training or insurance. This situation really puts patients at risk," the group's president, Dr Gabrielle Caswell said.

Meanwhile, the safety of liposuction has also come under the spotlight this week, with an inquest underway into the death of a young Adelaide woman a few days after she had the procedure on her thighs and abdomen in 2008.

She died of multi-organ failure, after developing gangrene following her operation by cosmetic surgeon, Dr George Kerry.

Photo showing the extent of the patient's burns after laser therapy.

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Calls to regulate laser hair removal

REGULATORS are being accused of exposing patients to dangerous cosmetic laser treatments by refusing to crack down on untrained beauty therapists.

There are currently no restrictions in NSW or Victoria on the use of IPL (intense pulsed light) and lasers for beauty treatments such as hair reduction, lentigine removal and skin rejuvenation therapy, with operators free to set themselves up in business with no training.

There are long-running concerns that customers have experienced severe burns as a result of botched procedures, and that some of the treatments could mask skin cancers.

Last week, consumer group Choice said the rapid growth in treatments was being fuelled by cheaper technology.

"Laser and IPL machines used to cost hundreds of thousands of dollars and were operated by doctors and dermatologists. Now you can buy them for only a few thousand dollars," a spokeswoman said.

"With treatments averaging $65 per five minutes and a series of sessions required, permanent hair removal businesses are being set up in shopping centres and beauty clinics."

Recently the Australian Radiation Protection and Nuclear Safety Agency (ARPNSA) said there was not enough published evidence of the dangers of the technology to justify mandatory training or licencing.

But Dr Gabrielle Caswell, president of the Cosmetic Physicians Society of Australasia, said mandatory training for operators was needed. Denying the call was about turf protection, she added: "These treatments have a real potential to be harmful if not administered correctly — and there's no requirement for non-medical personnel to receive informed consent, so people often aren't aware of the risks."

She cited a 2007 Queensland Department of Health ministerial briefing, acknowledging "improper or unskilled" use of IPL could result in "severe burns, blistering, scarring and keloid" as well as retinal damage to the operator.

The NSW Statewide Burn Injury Service treated six patients for serious burns after cosmetic laser treatment in the past year.

AAP and Paul Smith

There are concerns over 'improper or unskilled' use of cosmetic laser treatments.

Newcastle Herald, Newcastle NSW
17 Mar 2012, by Jacqui Jones

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back

Ugly side of beauty

Call for industry regulation

COSMETIC TREATMENT

By **JACQUI JONES**
Health Reporter

HUNTER doctors want regulation to stop unqualified beauticians using lasers and other powerful equipment in cosmetic treatments that risked burns and scarring.

The Australian Radiation Protection and Nuclear Safety Agency is working with states and territories on controls of laser and intense pulsed light devices for cosmetic purposes.

Representatives from the beauty industry say qualifications have been added to diploma training for beauticians.

Lasers and intense pulsed light can be used for cosmetic purposes such as hair removal, skin rejuvenation and reducing visibility of blood vessels and skin pigmentations.

Broadmeadow phlebologist Simon Thibault, a doctor who deals with venous diseases, is concerned about advertising of laser and intense pulsed light treatment for "spider" leg veins.

Dr Thibault said surface leg veins were a medical condition requiring specialist treatment. Laser and intense pulsed light were not proven effective and could burn or discolour skin.

Dr Thibault said equipment cost up to $150,000, but cheap machines were available.

Newcastle cosmetic oculoplastic surgeon Eugene Hollenbach said beauticians were buying dodgy machines for as little as $5000 from China.

The powerful equipment, if used incorrectly, could cause burns and scars.

Dr Hollenbach said many centres offering laser and intense pulsed light treatment had no doctors on hand in case of complications.

Dr Thibault said while doctors had accreditation, safety training and expensive insurance, he was not aware of beauticians who did. He said regulation was needed.

Spokeswoman Coleen Shaw said the Advanced Association of Beauty Therapists was aware unqualified therapists were offering treatment.

Laser and intense pulsed light qualifications were added to the beauty therapy diploma offered through registered training organisations, she said.

Ms Shaw said while treatment could go wrong, it could also go wrong with a doctor.

An Australian Radiation Protection and Nuclear Safety Agency spokesman said a working group was being set up to determine the nature and scope of measures necessary to ensure safe use of laser and intense pulsed light devices.

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BEAUTY INDUSTRY UNREGULATED

Woman scarred by skin treatment

■ Kate Bastians

Perth women are being left with scars and severe burns caused by amateur beauty therapists performing a popular hair removal and skin treatment without proper training.

A Joondalup woman has told how her chest resembles a chequerboard of excruciatingly painful burns after receiving Intense Pulsed Light treatment for sun spots two weeks ago.

IPL is a popular treatment for the removal of hair, age spots, freckles, birthmarks and abnormal pigmentation. It involves an intense flash of light that penetrates the skin and kills hair or removes unwanted pigment while sparing the other tissue.

The woman, who received the treatment from a woman who had set up a home business, feared she would be scarred for life and wanted to warn others about the complications that may arise from the treatment.

"It's ruined my social life and I have to wear high-collared tops all the time," said the woman, who does not want to be named. "I feel like a leper."

The WA Australian Medical Association and the Cosmetic Physicians Society of Australasia have called on the Health Department to introduce standards for the booming IPL industry, which is unregulated.

> 'There are too many cases where people are getting badly burnt.'
>
> **Chris Goodwin**

A CPSA survey found almost one in four of those who had a non-surgical cosmetic procedure had opted for laser or IPL treatments for permanent hair removal while a further 31.5 per cent of respondents said they would consider having IPL or laser hair reduction treatments in the future.

The Department of Consumer Protection received 21 inquiries and 10 complaints about IPL last year, which included reports of burns and scarring. That was up from 15 inquiries and one complaint in 2010.

Chris Goodwin, director of the Australian College of Beauty Therapy in Perth, said people were buying cheap IPL machines off the internet and using them on people without appropriate training.

"They think it sounds like a great money-making exercise and they get two days training and that's it," she said. "There are too many cases where people are getting badly burnt and I think the Health Department needs to act."

AMA WA vice-president Richard Choong said there had been an increase in reports of people receiving burns from IPL treatment as it became more readily available.

"I don't believe the Health Department has responded appropriately to this," he said. "If they don't act quickly and soon, then more and more of the public will be injured and scarred through these therapies."

Dr Choong and Ms Goodwin called for mandatory training for IPL machine operators and a set of standards to be introduced for the machines themselves.

Attempts at regulation have hit a stalemate.

A spokesman for the Health Department said it was waiting for the Australian Radiation Protection and Nuclear Safety Agency to develop nationally agreed standards before it moved to regulate the industry.

"If standards are significantly different across each State and Territory, then regulation is ineffective," the spokesman said.

A spokesman for ARPANSA said it was unable to adopt regulatory proposals until all the States agreed on a set of standards.

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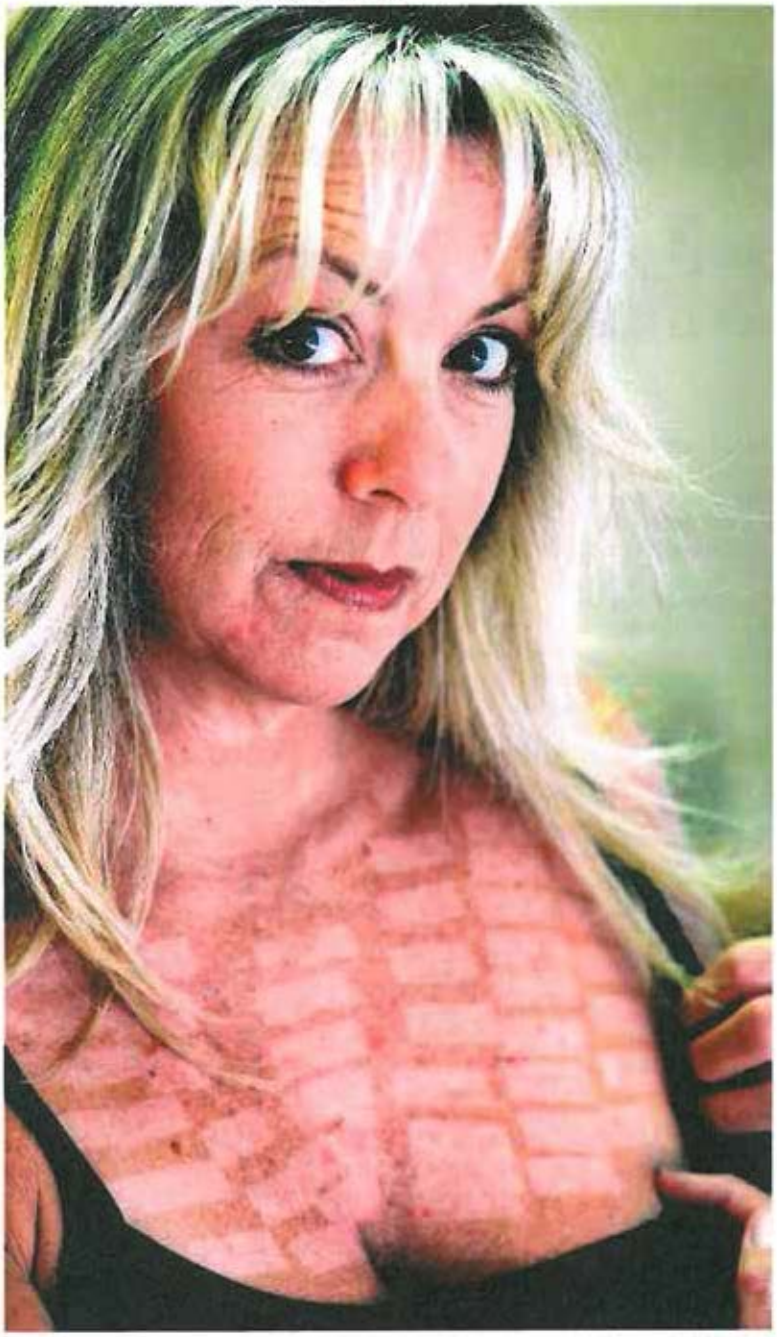

Painful: A Joondalup woman suffered severe burns. Picture: Sharon Smith

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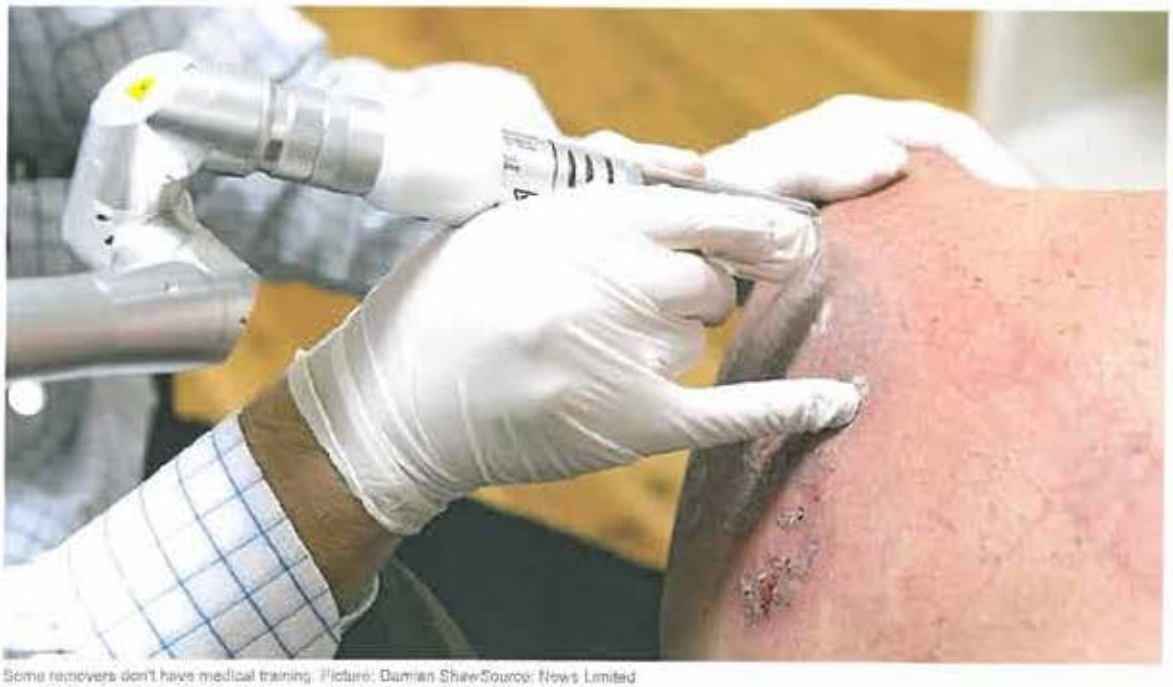
The dark side of the tattoo removal industry



Some removers don't have medical training. Picture: Damian Shaw Source: News Limited

TATTOOED Australians who regret their ink are being a put at risk of permanent skin damage because laser tattoo removalists aren't required to have medical training.

Tattoo removal is a booming industry - there's no shortage of potential customers.

Being able to undo what was once considered irreversible without extreme measures is good news. The tool of choice these days is a laser, which can and has caused burns and permanent scars on tattoo removal patients, *CHOICE reports*.

Some removers use medical-sounding assurances such as "certified laser practitioner" or "accredited clinician", which generally means they took a course offered by the laser maker, often a prerequisite for obtaining liability insurance. But that doesn't mean they're any good at removing tattoos.

In September last year, the then honorary secretary of the Australasian College of Dermatologists, Dr Cathy Reid, raised concerns about the use of lasers by people who lacked medical training and called for a national regulation regime. So far, that hasn't happened.

Removal techniques have come a long way since the days of skin grafting, skin removal or the use of infra-red and other non-medical lasers. Best practice these days dictates that unwanted tattoos be gradually broken apart through the use of Q-switched lasers set to specific wavelengths depending on skin type and the colour and location of the tattoo.

@choiceaustralia and @newscomauHQ want to hear about your #tattoolove or #tattoohate. Do you have #tattooregret? Tweet us with a picture.

The lasers are used in short bursts that break up the ink; the immune system then goes to work and gets rid of the dispersed particles over the course of many months and treatments (up to 15 treatments, six to eight weeks apart, for multicoloured tattoos).

Hilary Quinn, proprietor of Melbourne Tattoo Removal in the suburb of Caulfield, has been in the business for five years and says she's seen more than a few burns and scars on patients who came to see her after suffering at the hands of an unskilled remover.

acquire over time, and you need to approach it like an apprentice and build up your technique under the guidance of an experienced remover.

"The industry has really boomed, especially in the past six months or so, and unskilled practitioners far outweigh skilled ones. I know of many would-be tattoo removers who got a cheap laser machine, started off with little or no training, damaged a few people, and then got out of the business."

Dr Philip Bekhor, director of the Laser Unit at Melbourne's Royal Children's Hospital, backs up Quinn's assessment.

"In Victoria your local butcher could sideline in laser tattoo removal, and many removers scar up a lot of patients before they develop any real skill. In reality the process is extremely slow, not every colour responds well, and it can be painful. It's an invasive procedure with the capacity for injury," Dr Bekhor said.

Both Dr Bekhor and Ms Quinn say widespread use of cheaper knock-off versions of the Q-switched laser or, worse, the use of IPL lasers, are a principal cause of injury and unsuccessful tattoo removal. It's no coincidence that proper Q-switched machines cost about $150,000, while IPL lasers go for between $10,000 and $15,000.

The lower costs of getting into the business in recent years, along with the longstanding lack of regulation in many jurisdictions, are key reasons for the big increase in the number of tattoo removers, both say.

The problem, Dr Bekhor argues, is that "IPL lasers function in milliseconds instead of nanoseconds, and the wavelength is too broad. They're marketed as an all-purpose machine, including tattoo removal, but shouldn't be used for that purpose. They often cause distorting of the tattoo and horrific burns and scars."

. Quinn makes the same point. "Every second beautician seems to be offering tattoo removal with an IPL laser these days. It shouldn't be used for that. It shoots a block of light of about two by six centimetres rather than the five to eight millimetre pinpricks of Q-switched lasers. It's like trying to crack an egg with a machinegun."

Tattoo removal businesses booming

Belinda Williams October 07, 2013

Tattoo removal - before shot, provided by Dr John Flynn

But inconsistent regulation is putting consumers at risk of burns and scarring.

Businesses selling tattoo removal procedures are thriving in a society where tattoos are everywhere. Yet there is little oversight about how they are removed, leading to serious burning and scarring.

Tattoo parlours have just been regulated and now, some are calling for regulation of tattoo removal.

The problem with unsafe tattoo removal involves the use of intense pulse light (IPL) equipment, which doctors warn is not suitable for tattoo removal. Despite this, a brief internet search yields many small businesses selling tattoo removal with IPL.

Dr John Flynn, censor in chief of the Australasian College of Cosmetic Surgery, says tattoo removal cases at his private clinic in Queensland are increasing at a conservative estimate of 10 to 15 per cent a year. "It reflects the number of people with tattoos," he says.

Flynn says the boom in tattoo removal started not long after tattoos became de rigeur. he says people don't put enough thought into how they might remove a tattoo if they change their mind.

"We constantly have people come in with a very cavalier attitude and they think it's like rubbing it off a whiteboard. After schoolies week up here on the Gold Coast we have a procession of parents dragging their kids in by the ear saying 'look what they've done. Get rid of it.'"

Risks and costs

Flynn says the main problems associated with tattoo removal are the risk of scarring and infection, the need for multiple treatments and cost.

"One of the clinical problems is when you have multi-coloured tattoos. There are some colours that are far more difficult to remove than others, like lilac, aqua blue, teal green, purple or yellow. The colours loved by girls with their dolphins and butterflies are exactly the ones that are the hardest to remove."

"A lot of girls...have tattoos on the top of their foot or the inside of their wrist. Now the skin there is very, very delicate and so the risk of permanent scarring is much higher in those areas, and it's exactly the areas that are very visible and very hard to cover," Flynn says, adding that a five centimetre by five centimetre tattoo costs about $180 per treatment, with the number of treatments dependent on how heavy the tattoo is and the number of colours.

"It could take two to five treatments – that's the most common – but there are some tattoos that will take you 20 or more." That's a cost of $3,600 to remove one tattoo, which may have cost less than $100.

"Some colours are much more difficult to remove so you can only get a much smaller percentage removed each time. Whereas if it's an indigo or a black tattoo you'll get a large percentage removed each time and the number of treatments for that will be much smaller," he says.

No rules or regulations

Flynn practises in Queensland, one of only three states regulating the use of high-powered class 4 lasers for medical and cosmetic purposes.

He finds it staggering most states don't regulate class 3B or 4 lasers – powerful machines that can cause serious burns and turn people blind if not used correctly. Class 4 laser beams can even start fires.

"You could go buy a laser and then tomorrow get your aunty or your uncle to set up shop as a tattoo removalist. In some states there is no law against that. It's a real worry," he says.

Tasmania is the only state to have regulated IPL for cosmetic purposes. Light produced by IPL sources is not as targeted as lasers. For this reason it's not suitable for tattoo removal.

"IPL doesn't require the licensing laser does, and so there's a lot of people out there who can buy an IPL machine and if they don't understand IPL is different to laser, then they'll start trying to take tattoos off the same way they might try and remove wrinkles or hair. We've got patients coming in and they've got bad scars and you ask them 'what treatment did you have?' and they say 'I had that IPL laser'. Well excuse me, but IPL is not a laser," Flynn says.

Changes coming, but who knows when

Facial plastic surgeon Dr Jayson Oates, past president of the Australasian Academy of Facial Plastic Surgery, says tattoo removal at his Perth clinic is increasing by 20 per cent a year.

Oates had hoped the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) would release a nationally consistent set of rules later this year, to include training, registration and insurance requirements. But this is unlikely given

ARPANSA is yet to agree on a proposal – despite calls from doctors, including Oates, for years.

Oates practises in Western Australia, where class 3B and 4 lasers are regulated. He says only doctors can use lasers in WA, compared with New South Wales, where he says "your taxi driver can walk in, buy a laser and start up a clinic tomorrow. It is bizarre . . . especially when these are powerful, powerful machines."

But he believes the laws in WA are too draconian, which has contributed to the increasing use of IPL for tattoo removal.

"In WA the excessive regulation means there are very few tattoo removal lasers and we see the complications of people using IPL inappropriately and causing burns and scars. People are going to beauty therapists to have IPL that have been sold to them often by online Chinese companies who say 'these will take off tattoos'," says Oates.

"Well they will – with a big burning chunk of flesh that leaves a massive scar," he warns.

Oates says people are being scarred as a result of excessive regulation. "But at the same time we don't want to see it go the other way. I don't want to see a laser on every corner." Oates says there should be a transition period for businesses to adapt to any new laws.

In the meantime, Oates says his clinic is trying to keep up with demand. "It just keeps getting busier and busier . . . tattoos are incredibly popular, but people changing their mind is incredibly common as well."

The Therapeutic Goods Administration regulates the supply of lasers, IPLs and other devices for 'therapeutic purposes', but the Australian Register of Therapeutic Goods (ARTG) does not cover devices used solely for 'cosmetic purposes'.

The Australian Radiation Protection and Nuclear Safety Agency (ARPASNA) is a lead stakeholder. The agency's Radiation Health Committee (RCH) formulates draft national policies, codes and standards for the promotion of uniform national standards of radiation protection for consideration by the Commonwealth, states and territories.

The issue of lasers for cosmetic use was noted in an RCH summary report of a meeting held in July 2000. However 13 years on, little has changed – apart from the number of untrained people that now wield the powerful equipment.

An ARPANSA spokesman told Fairfax Media the timeframe for any regulatory changes and the number of businesses that would be affected was "unknown at this stage".

The spokesman said: "ARPANSA is working with state and territory regulators through the Radiation Health Committee (RHC) to develop nationally consistent and appropriate control of the use of lasers and IPLs for cosmetic purposes.

"Injuries to clients may occur because of incorrect use, however statistics have been difficult to obtain. The working group is gathering up-to-date injury statistics and will be required to provide a clear case for any regulatory proposal.

An RHC working group has been established to assess the options – these could include education, training and/or regulation.

ARPANSA says: "the working group has medical and beauty industry representation as well as representatives from a number of radiation regulatory bodies. As the working group has not yet provided its recommendations to the RHC, no proposal for regulation has yet been agreed upon.

"Before any set regulatory elements can be agreed at a national level, a period of public consultation would need to be undertaken and approval at ministerial level gained. Even once agreed, it would take some time for these regulations to be made into law and applied across all jurisdictions".