



Analysis of Public Submissions

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



Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



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Executive summary

Lasers and intense pulsed light sources (IPLs) have been in use in the cosmetic and beauty therapy industry (the industry) for a number of years. Their use for cosmetic and beauty therapy purposes involves the treatment of symptomatic (e.g. dark skin discoloration, superficial vascular conditions) and non-symptomatic (e.g. hair removal, skin rejuvenation) problems or medical conditions.

There is a common public perception that cosmetic medicine using laser and IPL techniques is quick, easy, painless and low risk. However, many procedures are complex and require a high level of application skill and experience, aesthetic appreciation and after treatment care.

A wide range of operators provide services with lasers and IPLs. Many are qualified professionals who are trained in the use of lasers and IPLs for cosmetic purposes, however, services are also provided by operators with limited or possibly no training. The devices used for cosmetic treatments are not necessarily approved by the Therapeutic Goods Administration and are easily available for purchase directly from distributors via the Internet, sometimes at low cost.

Media reports have highlighted injuries resulting from IPLs and laser treatments that have gone wrong. This has been accompanied by repeated calls for regulation of the industry. Currently, lasers used for cosmetic purposes are regulated in Queensland, Western Australia and Tasmania, and IPLs are regulated in Tasmania. There are some differences in the way each of these States regulate in this area.

In 2012 a Laser/IPL working group was established by the Radiation Health Committee to examine the options for how to promote the safe use of cosmetic lasers and IPLs in the industry. This resulted in the development of a Consultation Regulatory Impact Statement (RIS) in the use of Intense Pulsed Light (IPLs) Sources and Lasers for Cosmetic or Beauty Therapy that was released for public consultation in 2015. The Consultation RIS contained three models as options for promoting safety in the industry. These included education, self-regulation and accreditation by the industry or licensing of practices. It was intended that an analysis of the submissions from stakeholders would then be used to develop a Decision RIS.

A detailed analysis was undertaken of the 241 submissions received from stakeholders in the consultation process. The analysis showed that the submissions did not provide any significant additional quantitative information relating to the implementation of one or a combination of the options presented in the Consultation RIS. However, it did highlight an industry wide preference for some level of oversight to be implemented, with the major driver being public safety and positive health outcomes.

Consequently, it was concluded that there was insufficient information to substantiate the cost versus benefit estimations that would be required for a Decision RIS to be developed based on the options presented. Instead, it was decided that a nationally uniform approach could be promoted by the development of guidance material for the use of lasers and IPL devices in the industry. The guidance material would provide a common framework for terminology, education, training, equipment, patient care and injury reporting that would be accessible to the Australian public and which could be promoted by all States and Territories.

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1. Introduction

1.1 Background

Lasers and intense pulsed light sources (IPLs) have been in use in the cosmetic and beauty therapy industry (the industry) for a number of years. Their use for cosmetic and beauty therapy purposes involves the treatment of symptomatic (e.g. dark skin discoloration, superficial vascular conditions) and non-symptomatic (e.g. hair removal, skin rejuvenation) problems or medical conditions.

There are currently a growing number of businesses in Australia offering cosmetic procedures and beauty therapy through the use of lasers and IPL devices. The services most commonly provided across the industry include:

- hair removal
- removing skin blemishes such as birthmarks, lesions, acne and acne scarring
- treatment of superficial vascular conditions
- reducing the visibility of skin pigmentation
- rejuvenating skin
- tattoo removal.

The application of these techniques to treat the various conditions listed show varying measures of success. The use of lasers and IPLs to achieve the desired results is accompanied by hazards associated with using such powerful sources of visible to near visible light.

Lasers used for cosmetic purposes produce an intense beam of light consisting of a single wavelength (colour) of the spectrum. The laser beam is applied to the desired area for treatment and selectively damages specific targets (e.g. melanin in hair follicles, capillaries or tattoo pigment in the skin). The treatment area then recovers naturally in order to deliver the desired skin treatment outcome.

When used for the purposes of applying the range of treatments available, lasers need to produce sufficient power to have the desired effect. The lasers are typically of a Class 3B, and more commonly, a Class 4 power output. These 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*. Lasers with these high power outputs are capable of causing eye injuries and can also cause skin burns.

Unlike lasers, IPLs produce a beam of broad-spectrum light (white light), which may be pulsed and filtered to produce the desired cosmetic outcome. The light produces more generalised effects on the skin, such as improvement in some forms of brown and red skin pigmentation. IPLs are also widely used for hair reduction.

1.2 Health implications

There is a common public perception that cosmetic medicine using laser and IPL techniques is quick, easy, painless and low risk. However, many procedures are complex and require application skill and experience, aesthetic appreciation and after treatment care. As noted, the use of lasers and IPLs is based on causing deliberate, targeted damage to areas of treatment, relying on the body's natural healing mechanisms to repair the affected area to deliver the desired cosmetic result. This mode of treatment can pose several risks when the procedures are not applied correctly or when they are applied to clients who are not appropriate candidates for the desired treatment.

A wide range of operators provide services with lasers and IPLs. Many are qualified professionals who are trained in the use of lasers and IPLs for cosmetic purposes, however, services are also provided by operators with limited or possibly no training. The devices used for cosmetic treatments are not necessarily approved by the Therapeutic Goods Administration and are easily available for purchase on the internet, sometimes at low cost. The relative ease in accessibility has resulted in a situation where consumers can receive cosmetic treatments using IPLs and lasers from operators who do not have a proper understanding of the risks involved in applying the treatment, and who are using equipment which may be substandard or poorly maintained.

The consequences of incorrect treatments can range from minor burns to severe injuries requiring follow up medical treatments and leading to permanent scarring in the affected areas. Treatments conducted near the eyes could also lead to eye injuries and vision impairment. Even more seriously, there have been cases where cosmetic therapies have been used inappropriately to treat the symptoms of malignant skin conditions including melanoma, effectively masking or removing these symptoms. This has led to several documented instances of late or missed diagnosis of these serious underlying health problems.

Media reports have highlighted injuries caused by IPLs and lasers resulting from incorrectly applied treatments. These have been accompanied by repeated calls for regulation of the industry. In 2012 a Laser/IPL working group (working group) was established by the Radiation Health Committee (RHC) to examine the options for how promote the safe use of cosmetic lasers and IPLs in the industry. Initially, the working group developed an online survey which was responded to by an estimated 10 % of the industry. The survey identified 416 cases of injury over the previous twelve months with 268 injuries being classified as severe. There were 62 reported cases where the diagnosis of skin cancer was delayed or missed and in 22 of those cases the cancer was identified as melanoma. Although this data was limited, the survey report was used to provide further guidance to prepare a Consultation Regulatory Impact Statement (RIS) in the use of Intense Pulsed Light (IPLs) Sources and Lasers for Cosmetic or Beauty Therapy (Consultation RIS) (ARPANSA 2015).

1.3 Current regulatory framework

Currently, lasers used for cosmetic purposes are regulated in Queensland, Western Australia and Tasmania, and IPLs are regulated in Tasmania. The regulations in each of these states are not the same. Both registered medical practitioners and non-medical operators in Tasmania and Queensland need a licence to operate lasers for cosmetic purposes. In Tasmania a licence is also required to operate an IPL device for cosmetic treatments. In Queensland non-medical operators must be supervised by a registered medical practitioner for all procedures except for hair removal where they are required to follow the advice of a registered medical practitioner. In Tasmania, there is a requirement for non-medical operators to have a documented association with a registered medical practitioner for the purposes of pre and post

consultation with clients if required. In Western Australia, all operators of laser devices must be registered medical practitioners, however, non-medical operators may use the lasers under the direction of a registered medical practitioner. The remaining state or territory jurisdictions have not introduced regulatory frameworks for oversight of the use of lasers and IPLs for beauty therapy and cosmetic treatments.

1.4 Options presented in the Consultation RIS

Stakeholders were invited to consider and submit comments on three options for oversight of the industry to implement. These options were:

Status quo – no changes to current national practices:

This was presented as the current status in the industry for stakeholders who believed no changes to current practices were necessary. This option would leave in place the current situation of different regulatory expectations of the industry across the country. The only common recourse available to consumers who are injured as a result of incorrect treatments would be legal in nature under consumer laws.

Option 1 – Educational Awareness:

In this option, educational awareness would be promoted by the use of factsheets, brochures and public health campaigns aimed at making the general public more aware of the risks involved in the range of treatments offered. The advice would focus on aspects such as appropriate operator training for certain procedures, hazards from laser and IPL radiations, medical clearance for treatment of pigmented lesions, quality of the treatment devices used, etc. This option still relies on legal recourses for any injuries sustained from incorrect treatments.

Option 2 – Self-Regulation by Industry/Industry Accreditation Scheme:

This option requires operators to develop guidance material that governs good practice in the use of lasers and IPLs across the industry. This guidance material would then form the basis for a voluntary accreditation scheme. The standards employed would have to be agreed to and consistently implemented by the various sectors of the industry. However, accreditation would not be mandatory under this scheme. At best, it may serve as a point of reference for the public and deter a number of consumers from seeking treatment from providers that have not been accredited. The guidance itself would cover aspects of practice similar to those outlined in Option 1.

Option 3 – Licensing (or Registration) of Service Providers:

Under these conditions only operators with appropriate training and experience would be able to apply laser and IPL treatments to patients. Treatment types would be divided into categories where the training requirements differ depending on the treatment type to be administered. For example, more complex procedures such as skin resurfacing and tattoo removal would be restricted to registered medical practitioners or clinicians working under their supervision. Licensing would be based entirely on qualification and the level of training and experience needed for each category of treatment. The base level of qualification required to apply any treatment would be at Level 7 (bachelor degree) in accordance with the Australian Qualification Framework. Clearance from medical professionals would also be mandatory before treatment of any pigmented lesions (ARPANSA 2015). The adoption of this option by all Australian jurisdictions would result in uniform standards and regulatory expectations across the entire industry.

1.5 Objectives of Consultation RIS

The objectives of the regulatory impact statement released for public comment in 2015 were to:

- outline the real and perceived health risks associated with the lack of national consistency in the standards applied for the use of lasers and IPLs in beauty and cosmetic therapy
- promote a nationally consistent approach to the delivery of services in the industry
- gather additional information about current practices, stakeholder views and experience across Australian jurisdictions
- invite stakeholder consultation on perceptions of the industry, the current standards, practices and business and health risks
- measure support for the options proposed in the Consultation RIS for the way forward for the industry
- use the information gained to inform the working group and RHC on a decision for the way forward in promoting public safety and a nationally uniform approach in the industry
- decide on the work programs necessary to progress the process for any decision taken as a result of consultation process, or to fill any knowledge gaps highlighted by the stakeholder submissions.

1.6 Scope

The Consultation RIS was drafted by the working group and was released for public consultation from May 2015 to the end of July 2015. This generated over 260 responses, of which 241 were identified as being valid after review and initial scrutiny removed repeated, blank or irrelevant submissions. The contents of these submissions was used to inform the working group and RHC in making a decision on the appropriate way forward in addressing the real and perceived health implications posed by the use of lasers and IPLs in the industry.

The anticipated Decision RIS would be based on the evidence presented in the Consultation RIS and the stakeholder submissions received. Following the outcome of the consultation and a decision by the RHC, the anticipated Decision RIS was expected to be released for public consultation.

It is the intention that the option identified as being the preferred way forward would be implemented across all Australian jurisdictions after resolution of the Decision RIS. However, implementation of this preferred option may not occur in jurisdictions where regulation is already in place.

2. Methods

2.1 Analysis of public submissions

The Consultation RIS requested comments and feedback on specific issues outlined within the document. As stated in the Consultation RIS, stakeholders were invited to:

- provide feedback on whether the nature and magnitude of the problem presented was accurate. If not, stakeholders were asked to provide additional details to add to or correct the information
- provide their views on the significance of the problem in jurisdictions that do not regulate IPLs and lasers for cosmetic or beauty therapy

- comment on the options described in the Consultation RIS and suggest other feasible options to achieve the objective of reducing the number of serious injuries from the commercial use of IPLs and lasers
- provide feedback on the assumptions used to estimate the costs of consumer awareness campaigns, operator training, the production of guidance documents and the benefits of Option 1 (educational awareness)
- provide feedback on the assumptions used to estimate the costs and benefits of Option 2 (self-regulation through a voluntary accreditation scheme)
- provide feedback on the percentage of the industry that has adequate qualifications and the assumptions used to calculate this compliance cost
- provide feedback on the assumptions used to estimate the costs and benefits of Option 3 (licensing of operators)
- comment on the expected competition effects, in particular whether Option 3 would result in significant restrictions to competition. Where possible, stakeholders were requested to provide data to support their views
- provide feedback on whether there is a sufficient case for government intervention based on the nature and magnitude of the problem.

The 241 stakeholder submissions received were reviewed and their response to the consultation according to the points listed above were analysed. Most of the submissions highlighted a preference for one or a combination of the options outlined in the Consultation RIS. Therefore, it was considered an appropriate starting point of the analysis to categorise the responses in terms of their support of each option. Where provided, the respondents' jurisdiction of practice and profession was also noted. Where this information was not provided, the working group researched the jurisdiction of the respondent from information contained within the response. This information was considered relevant in order to quantify jurisdictional representation in the consultation process.

The submissions were also analysed according to criteria which would assist in gaining a view as to the industry's position as a whole. To this end, a consistent set of reference questions were developed according to the recurring nature of themes observed in the responses provided by stakeholders. These were considered indicative of a strong stakeholder focus and a means of measuring the industry in terms of the implications of the Consultation RIS. This resulted in the development of analysis categories including:

- the specific level of support for the proposed options (i.e. full support, partial support, support with changes or not supported)
- support for educational requirements (degree, diploma, short course)
- 'grandfathering' (exempting current operators from the educational requirements put forward in option 3 of the Consultation RIS, in recognition of their existing qualifications and experience and safety record)
- any particular concerns in relation to the options as proposed
- equipment requirements (e.g. whether the laser/IPL devices should be registered with the Therapeutic Goods Administration (TGA) or whether the equipment or the premises themselves should be licensed).

Further, due to the repetition of the topics covered by these categories, their use in analysing the submissions was the only basis for comparison and quantifying the appetite of stakeholders for the options presented in the Consultation RIS.

2.2 Assessment methods

The responses were compiled into a 'comments resolution table' and analysed to gather information from the comments made in order to assist the RHC in determining the way forward. Each submission was assessed and the salient comments were categorised according to the broad themes discussed above. Once appropriately assigned to the categories, an analysis was performed to determine the level of support for the proposed options and gain additional information regarding any other concerns raised.

This process was conducted by a small team who split the submissions for review. Quality control consisted of cross checking the conclusions drawn from a representative number of submissions to assure that the each team member attained the same results. This was done both by open discussion to 'calibrate' the analysis and individual effort to assure reproducibility.

2.3 Assumptions and definition of analysis terms

There were some assumptions made during the course of analysing the results. As the contents of the submissions were broken down to fit into the particular categories of interest, terminology needed to be developed in order to accurately reflect the position taken by the respondents.

The support for each option was categorised as *Full Support*, *Partial/Modified Support*, *Does Not Support* and *No Comment*. Definitions of the terms used are provided below:

- *Full support*: The respondent commented that they fully supported the implementation of that option as proposed in the Consultation RIS.
- *Partial/Modified Support*: The respondent accepted the general concept of the option but provided additional details how it should be modified for implementation.
- *Does Not Support*: The respondent clearly stated that they did not support the implementation of that option.
- *No Comment*: There were no clear comments on the option for analysis.

The terms to qualify the nature and specific level of support for other analysis categories are also described below:

- education requirements (degree, 6-12 months course, short course, no change, no comment)
- grandfathering (does not support, supports, no comment)
- potential impacts/concerns (client safety, cost to business, cost/time for additional education, no comment)
- equipment/premises requirements (TGA/licensing, no comment).

3. Results

3.1 Analysis of respondents

The Consultation RIS generated a relatively large number of submissions from a wide range of stakeholders in every Australian jurisdiction. Stakeholders included:

- medical professionals (dermatologists, plastic surgeons, etc.)
- non-medical operators (beauty therapists, tattoo removalists, etc.)
- other medical (dentists)
- professional associations (e.g. school of dermatologists)
- laser and IPL device suppliers or manufacturers
- laser and IPL training course providers
- state and territory regulators.

It was noted that no responses were received from members of the general public or consumers.

The relative number of responses submitted by stakeholders can be seen in Figure 3.1. Out of the stakeholder groups that identified their profession or association, it was clear that non-medical operators of lasers and IPLs represented the largest number of stakeholders that submitted responses (55%) to the Consultation RIS. Registered medical practitioners, the majority of whom also worked in beauty therapy centres, were also highly represented in the mix (24%).

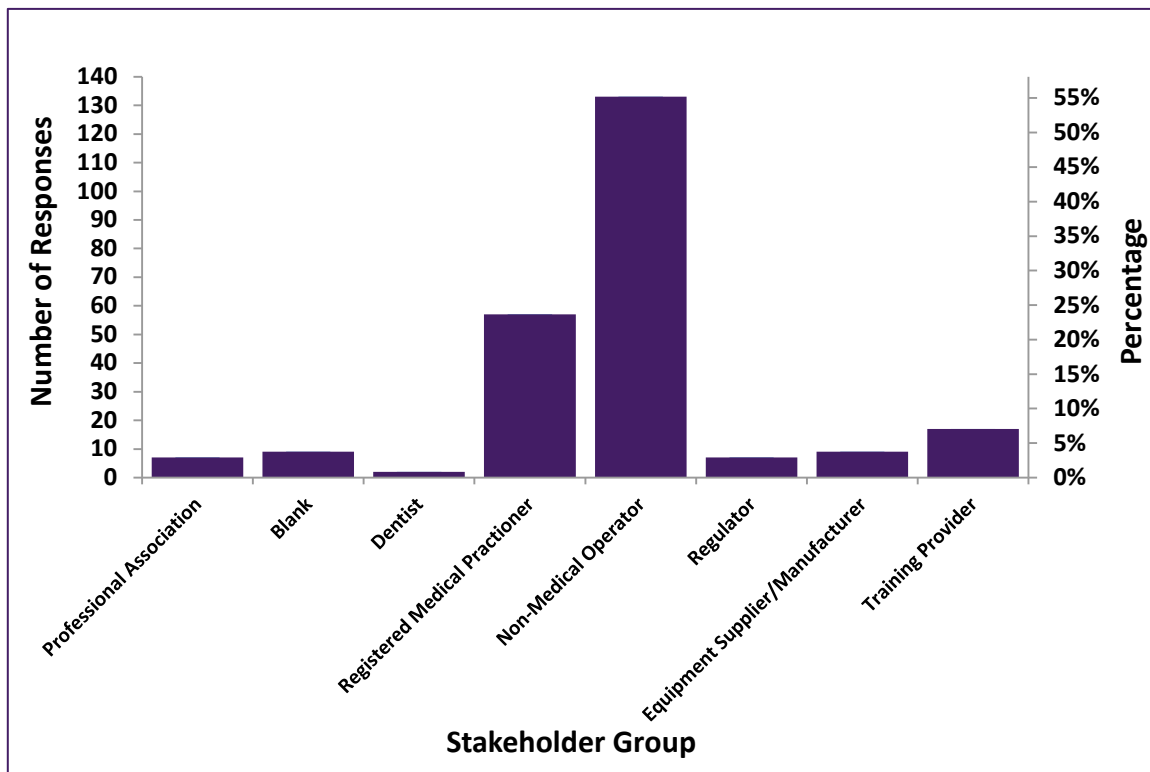


Figure 3.1: Number of responses by stakeholder group.

Jurisdictional information was either provided or determined for 79% of respondents. The relative number of responses by jurisdiction, shown in Figure 3.2, reflects that the majority of responses were generated from stakeholders in New South Wales (25%) with Queensland (19%), Victoria (15%) and Western Australia (10%) also showing a high response rate.



Figure 3.2: Relative number of submissions by state and territory.

3.2 Stakeholder submission analysis

Most of the submissions received from stakeholders focussed on the preference for the options presented in the Consultation RIS, effectively rendering the invited consultation as a vote for the future direction of any oversight in the industry.

Further, it was observed that a large number of the submissions received contained varying degrees of supporting evidence for their stated preference. Where reasoning for a preference was provided, several respondents justified their option preference citing concern for the future of their business should regulation in the form of Option 3 came into effect. On the other hand, it was noted that some submissions were identical and in the form of ‘proforma’ (standardised response sent in by multiple respondents with a common interest). While a preference for an option was strongly stated in these responses, no supporting evidence for their position was provided in the context of improved public safety. Furthermore, these submissions did not address any of the other topics opened for comment in the Consultation RIS. These proforma responses were identified as being provided by both medical professionals and non-medical operators. A single proforma type response was identified from a large number of medical professionals and there were two proforma type responses from non-medical operators. The two proforma types from the non-medical operators carried a similar message. Of the 57 respondents identified as medical professionals 72% provided the proforma response fully supporting Option 3. Of the 133 non-medical operator responses, 29% submitted proforma responses that either fully supported Option 2 or a partial/modified Option 3.

Forty-nine of the respondents provided a detailed response requiring further evaluation against the nine questions asked of stakeholders in the Consultation RIS. Very few of the submissions fully addressed the specific issues covered by the invited topics for consultation. Where these topics were covered, a handful of responses expressed concerns including:

- disagreement with the estimated cost for the training proposed in the RIS in order to comply with Option 3
- disagreement with the level of training required to perform certain procedures, in particular, skin rejuvenation, hair reduction and tattoo removal. In these cases, many of the submissions provided an account of their own business experience taking into account their own qualifications and safety record to justify their position
- disagreement with the extent and nature of the problem. In particular, there were a few comments which questioned the method of assessing the extent of the injuries caused by incorrect treatments, and even the actual number of injuries occurring
- concern regarding the motivation for proposed government intervention presented in Option 3. Although the RIS focused on health outcomes and safety for users of laser and IPL based cosmetic procedures, some stakeholders perceived that there was a hidden agenda of anti-competition by other stakeholder groups. In particular, many stakeholders considered the training levels required to be compliant with Option 3 to be ‘over the top’ and restrictive.

3.3 Feedback on the options presented in the Consultation RIS

While analysing the common themes of stakeholder feedback to the Consultation RIS more discernible trends were revealed. Figure 3.3 shows the support for each option if the information distilled from the responses is translated into a vote of the respondent’s preference. From this information it is clear that, overall, the majority of stakeholders were in favour of some form of regulation to be put into place. Although licensing as proposed by Option 3 had the most support (52%), self-regulation as proposed by Option 2 also gained support from 14% of respondents.

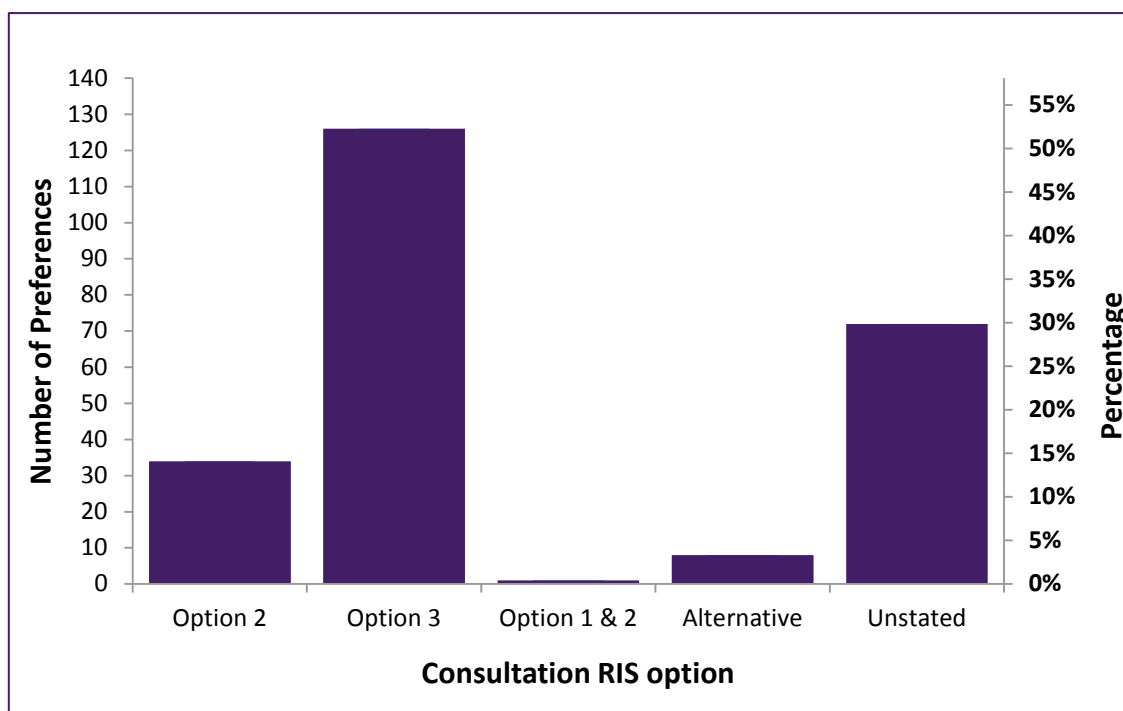


Figure 3.3: Results of stakeholder preference for the options presented in the Consultation RIS.

However, when the results were examined more thoroughly in the context of each individual option as described in the Consultation RIS the stakeholder position became less obvious and, indeed, more divided.

Figure 3.4 shows the level of support for Option 1. The majority of respondents made no comment about this option while those who did stated that they did not support Option 1 on its own. Some stakeholders noted, however, that this option could form part of the overall solution when combined with other strategies or the other options presented.

Figure 3.5 shows the level of support for Option 2. A relatively smaller proportion of respondents supported this option in full, with a larger group (33%) directly opposing it. The majority of respondents made no comment on this option. A number of respondents noted that this option was effectively similar to the status quo which has resulted in inconsistent training and service delivery standards, possibly contributing to the injuries outlined as part of the Consultation RIS.

Figure 3.6 shows the level of support for Option 3. While the results from the options put forward in the Consultation RIS indicated that Option 3 was the preferred model, the detailed review of the comments indicated that a lower number of respondents supported Option 3 in full (38%). The analysis showed that the number of respondents who supported a partial/modified version of Option 3 (27%) and those who do not support Option 3 (12%) were slightly higher (combined 39%) than those that fully supported that option. With regard to support for Option 3 it was noted that 82% of the registered medical practitioners who responded fully supported the proposed model, while only 24% of the non-medical operators who responded fully supported it.

Analysis of the 'does not support' and 'partial/modified support' for Option 3 showed that 46% of non-medical operators and 10% of medical practitioners provided comments expressing varying degrees of opposition to this option.

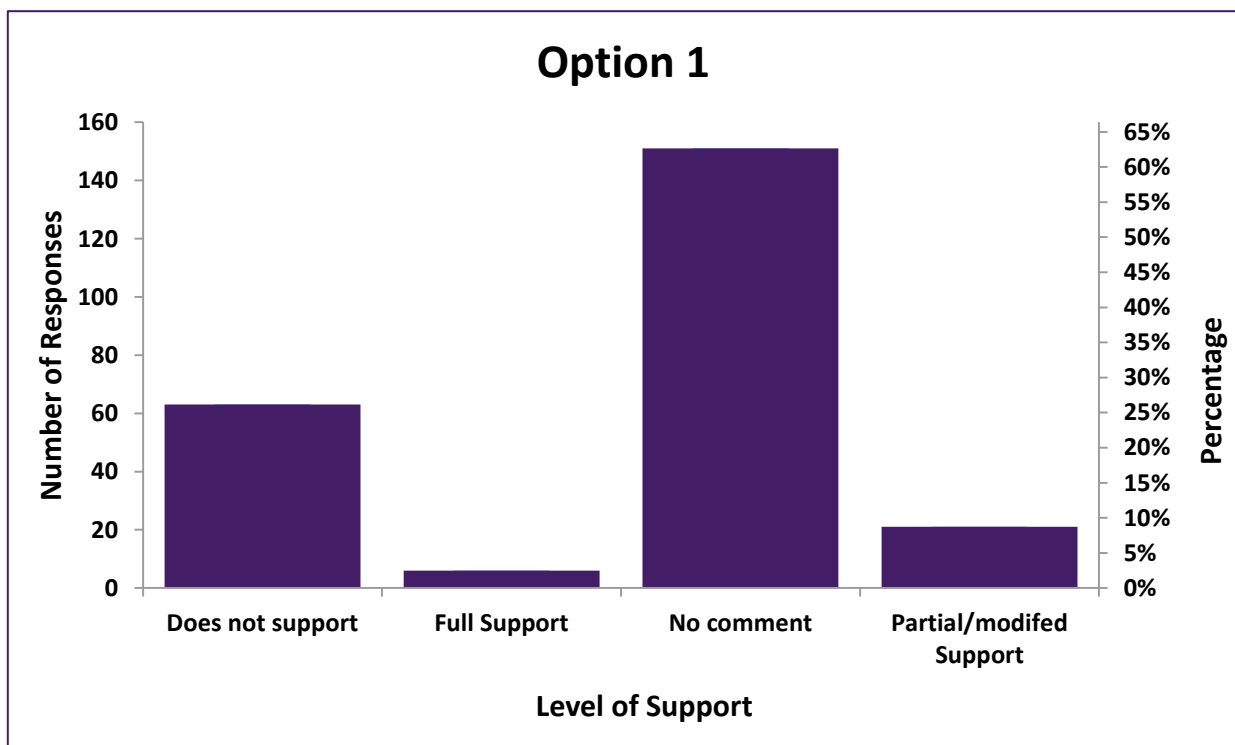


Figure 3.4: Level of support for Option 1.

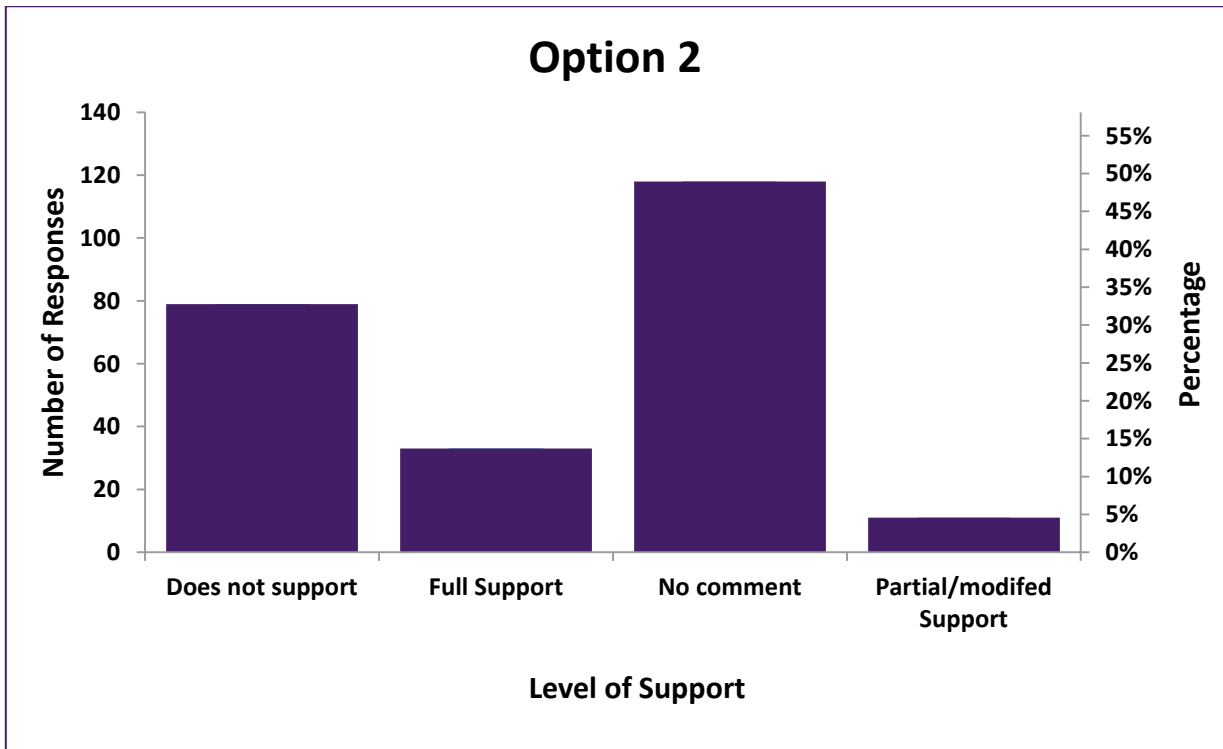


Figure 3.5: Level of support for Option 2.

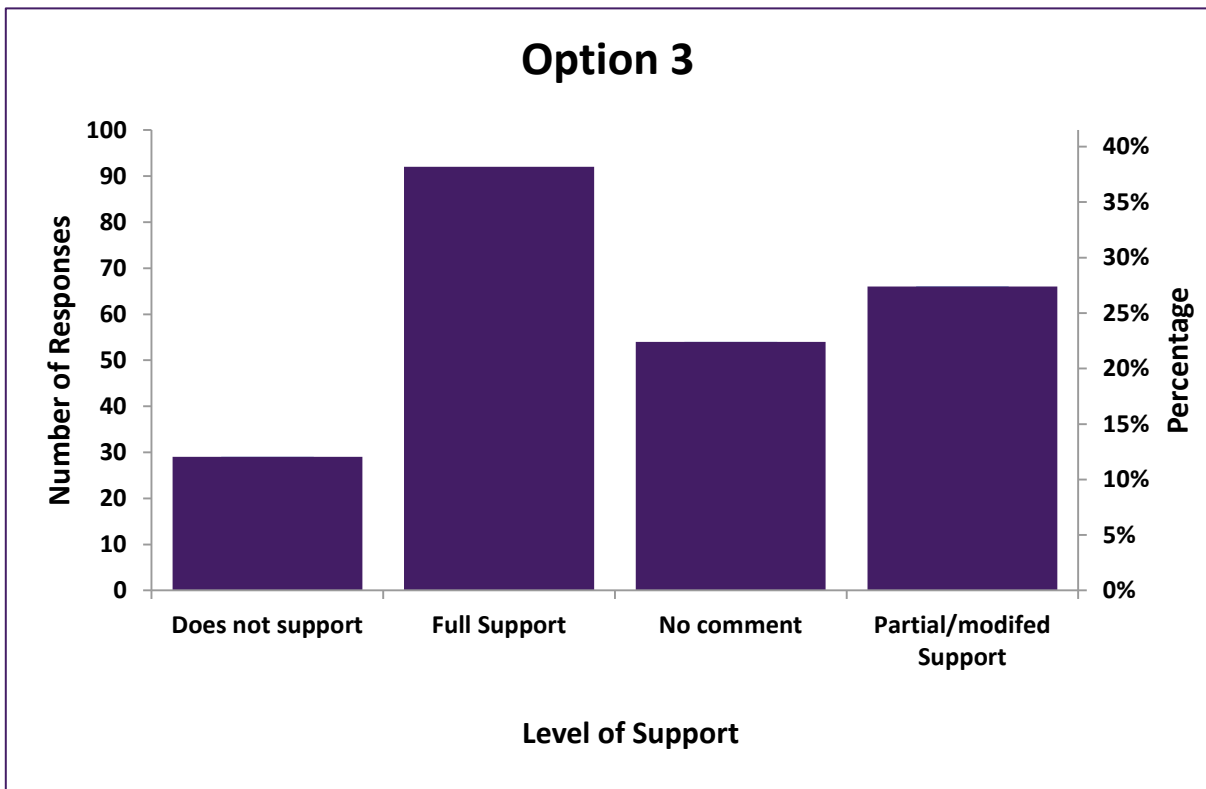


Figure 3.6: Level of support for option 3.

3.4 Additional assessment of submissions

Results were also generated from the further analysis undertaken on submissions regarding:

- appropriate level of education/qualification required
- grandfathering for people currently employed in the industry
- impacts/concerns associated with the proposals put forward in the Consultation RIS
- consideration of equipment/premises requirements.

Figure 3.7 indicates the level of qualification stakeholders felt was appropriate for the industry in general. As demonstrated, 98 of the 241 respondents were of the view that a degree level of education, rather than a shorter course or an advanced diploma, should be undertaken as a requirement to be considered appropriately qualified to deliver laser/IPL treatments safely. Of the 98 respondents who supported a degree, 49% were registered medical practitioners and 35% were non-medical operators., Of the 51 respondents supporting a 6-12 month course, 78% were non-medical operators and 4 % were registered medical practitioners. All who supported no change were non-medical operators, and those who supported short courses were non-medical operators (82%) and suppliers (18%).

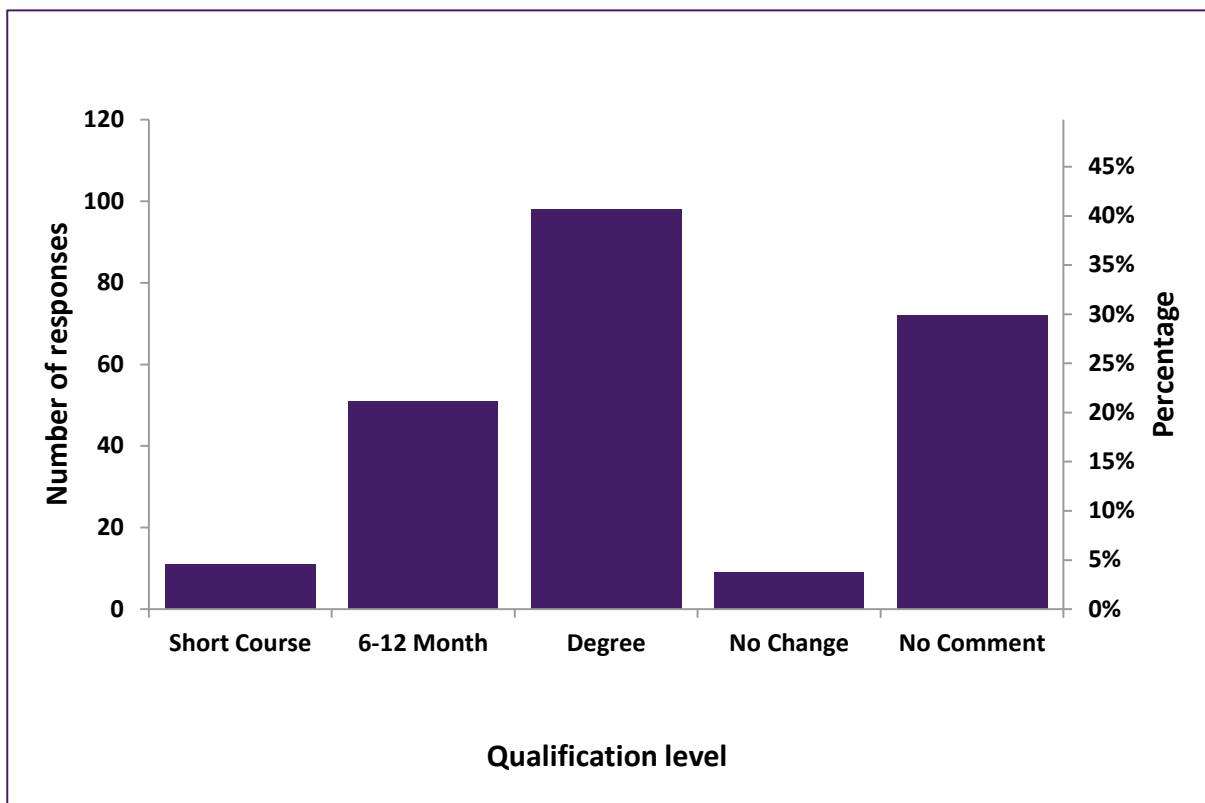


Figure 3.7: Stakeholder feedback for appropriate qualification levels to deliver laser/IPL treatments.

Grandfathering was not addressed in the Consultation RIS. However, it was raised as an issue by a number of respondents (14%) as shown in Figure 3.8. Of those who indicated their full support for grandfathering (12%), the majority were current operators (69%) that did not meet the requirements for licensing proposed by the model in Option 3. The respondents that offered any form of justification for this position cited their own safety record as evidence.

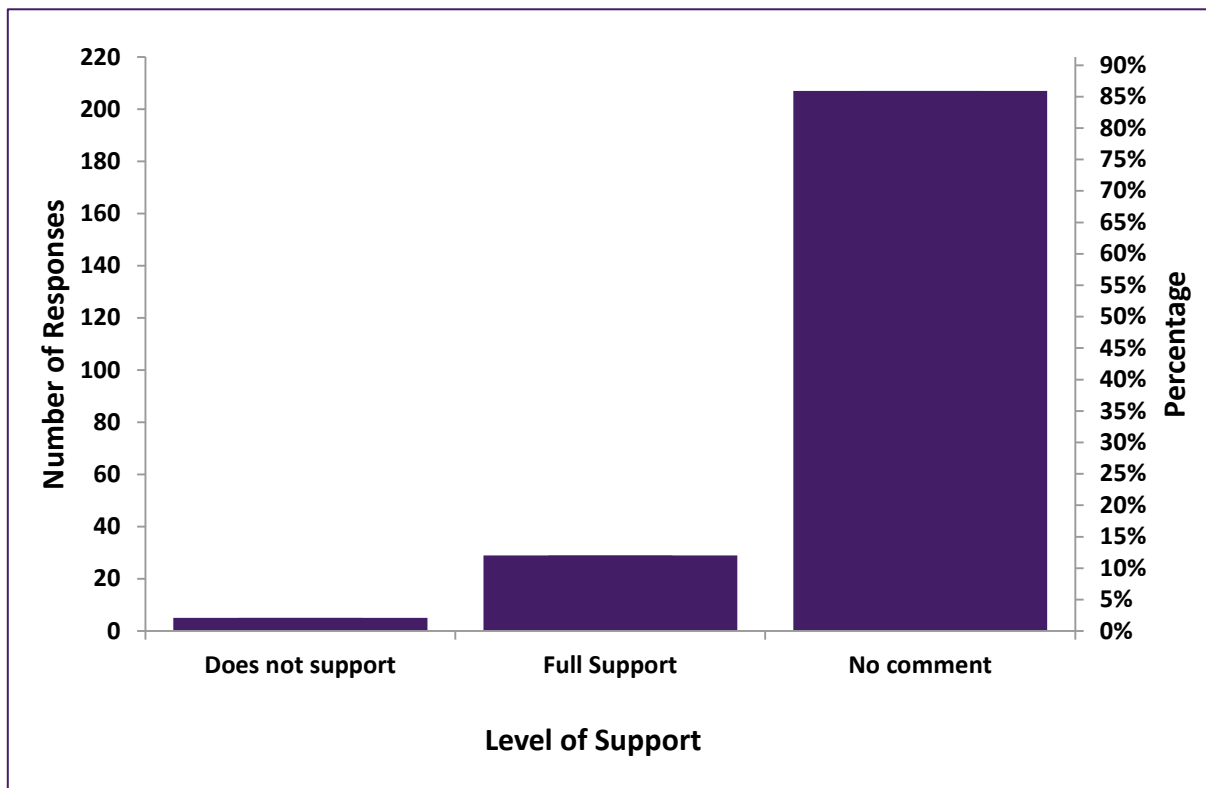


Figure 3.8: Stakeholder support for grandfathering of existing operators.

Thirty-eight per cent of respondents made comments that the proposed changes (in reference to their preferred option) would have positive impacts to improve client safety, or that client safety needed to be improved by making changes. Other respondents expressed concerns regarding impacts to their business, where business and training costs were specifically and often identified. Figure 3.9 shows stakeholder responses to specific matters in relation to potential impacts in the industry should regulation proposed in Option 3 be introduced.

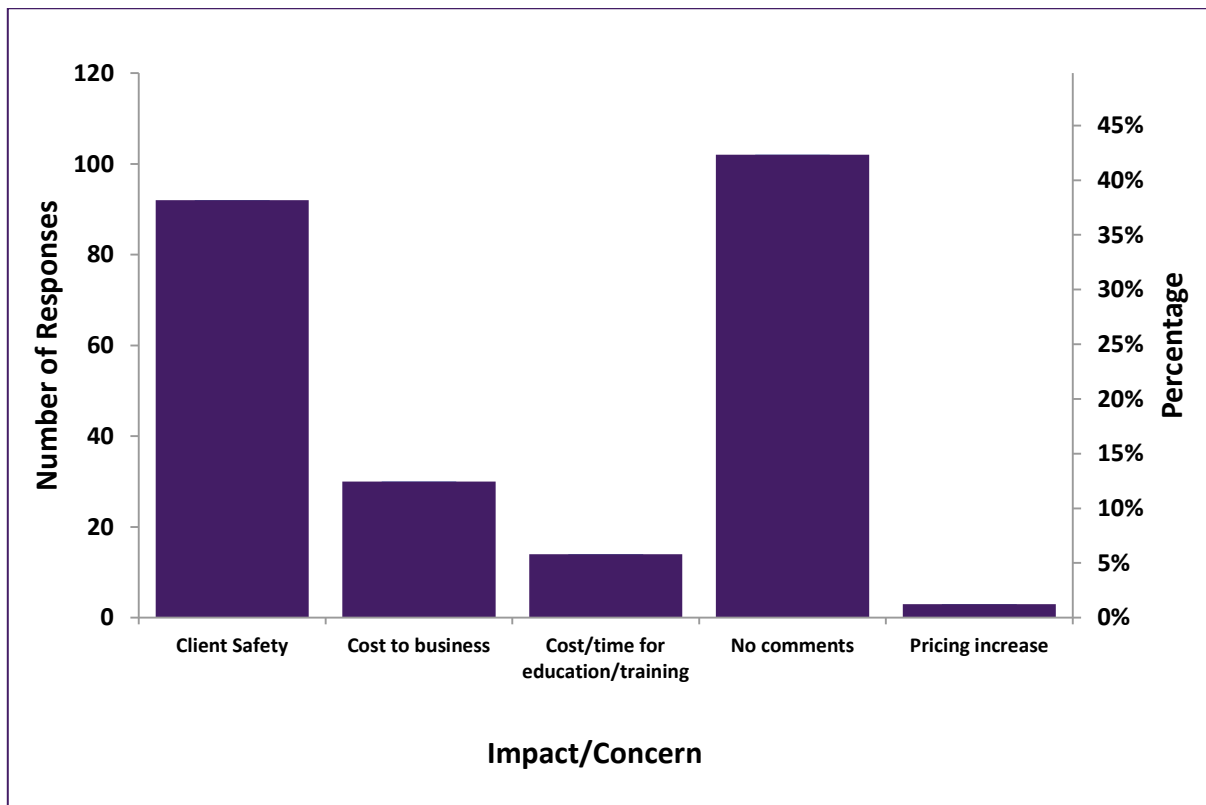


Figure 3.9: Stakeholder response to potential changes that oversight of the industry may imply.

A total of 20% of all respondents noted that some level of equipment approval (e.g. TGA approval) and/or premises licensing should also be required. The other submissions did not provide comment on this matter.

4. Discussion

4.1 Implications of the consultation

From the analysis of the 241 submissions, it was clear that very few of the respondents addressed any of the nine points invited for consultation, and those that did, provided responses that were mostly subjective or emotive. Some responses contained additional information disputing some of the data presented, mainly the estimated cost of training as proposed in the Consultation RIS. Although these were noted, there was an insufficient volume of responses containing evidence or traceable data that could be added to further enhance a snapshot of the industry beyond the data given in the Consultation RIS.

When compared with Australian population demographics from the Australian Bureau of Statistics (ABS), as shown in Table 4.1, it can be seen that the response rate to the Consultation RIS by jurisdiction was comparable to the population of each state and territory. This gives a reasonable measure that stakeholders were well represented nationally. Also, the consultation generated responses from a wide range of stakeholders (Figure 3.1). Despite this correlation, it is important to note that there were no submissions from consumers or consumer groups.

Table 4.1: Population demographics of Australia compared to Consultation RIS response rate by jurisdiction.

Jurisdiction	Percentage of National Population (ABS 2016)	Percentage of Responses to Consultation RIS
NSW	32	25
VIC	25	15
QLD	20	19
SA	7	5
WA	11	10
TAS	2	3
NT	1	1
ACT	2	1.7

It was decided by the working group that value could be gained by gathering data on the collective opinion of industry as a whole as to the way forward. This was achieved by measuring the preference by stakeholders for the proposed options for oversight presented in the Consultation RIS.

From the analysis, there was an indication that the industry supported some form of oversight or guidance (Figure 3.3). However, when the responses to Options 2 and 3 were examined more closely, it was observed that a large proportion of stakeholders supported the proposal conditionally, and suggested a range of modifications to the proposed model. This was particularly evident for Option 3. The essence of most responses, whether they fully or partially supported the models proposed, relied on an opinion to justify their position. Whatever the position taken, no new data was submitted supporting improved public safety in the context of their preference.

The data in Figure 3.9 indicated that the primary motivator for changes in oversight of the industry was client safety. Further, supporters of grandfathering clauses in any potential future regulation of the industry cited their client safety record as a justification for their position. These respondents provided data on the number of procedures they had performed compared with the number of injuries that were caused. This indicated an impressive safety record, however, it should be noted that the data was self-reported by the operators and not confirmed via independent reporting.

There was also division on the level of education considered to be appropriate for the application of laser or IPL treatments. Although the majority of stakeholders indicated that a bachelor degree level of education was required as a minimum qualification, a large number of responses pointed to short courses and advanced diplomas as adequate. Again, there was no additional data provided to demonstrate any effect on public safety based on level of qualification of operators.

4.2 Radiation Health Committee decision and rationale

From the results of analysis of stakeholder submissions, it could be seen that there was a strong push for some form of oversight for use of lasers and IPLs in beauty and cosmetic therapies. The main driver for this change was concern for client safety. However, in context of the options presented in the Consultation RIS, stakeholders were notably divided as to the model which would promote good practice while ensuring business continuity for non-medical operators of these devices

The injury statistics presented in the Consultation RIS were reliant on self-reporting by stakeholders. Further, the information was only captured from a small part of the industry (10%) and the survey responses came from a number of sources, some anonymous and some from indirect sources such as insurance providers and hospitals who only treated the injuries. Therefore, it is not clear what proportion of injuries were caused by medical professionals or non-medical operators from the information provided. The consultation process did not provide any significant information to address this knowledge gap.

Due to the significant gaps in knowledge concerning health outcomes and causes of injuries, and a lack of evidence and verified data, support for the adoption of any of the three options proposed in the Consultation RIS could not be justified. It was concluded that there was insufficient information to substantiate the cost versus benefit estimations that would be required for a Decision RIS to be developed and therefore the RHC agreed not to proceed with a Decision RIS.

However, due to the industry's overall agreement that some form of oversight should be put into place and due to inconsistencies in the terminology and perspectives given in the responses received, it was decided that there would be merit in producing a guidance material. This guidance material would be based on current good practice and safety standards in the application of laser and IPL treatments for beauty therapy and cosmetic procedures.

Although adoption of the guidance will not be mandatory, the objectives of this strategy are:

- to promote a nationally available and recognised safety benchmark for service providers in the industry to measure their own safety performance
- to assist consumers in making informed decisions as to which service providers they choose for their treatments.

The guidance material will contain information on matters relevant to safety in applying laser and IPL based procedures including, but not limited to:

- appropriate qualifications, training and experience recommended for certain procedures
- equipment and maintenance
- patient care including medical clearance of certain conditions before any treatment is applied
- laser and IPL radiation hazards to patients and operators
- injury reporting.

The guidance material will be accompanied by safety promotional material such as fact sheets, brochures and frequently asked questions aimed at informing the Australian public about the guidance material and outlining the hazards and potential health implications of undergoing laser and IPL based cosmetic therapy.

5. Conclusion

The Consultation RIS for the use of lasers and IPLs in the cosmetic and beauty therapy industry released for public comment in 2015 received a large volume of submissions from stakeholders. Unfortunately, no responses at all were received from consumers. A 'comments resolution table' was created from the 241 submissions, and from this a comprehensive analysis of the submissions received was performed. The analysis was undertaken by a working group that reviewed each submission. Very few respondents addressed the specific topics invited for consultation as outlined. Where these areas were covered, a qualitative overview was conducted and some of the major themes were extracted. The comments focussed broadly around aspects including:

- quality of injury data presented in the Consultation RIS
- competition implications to businesses if licensing in the form of Option 3 was introduced
- costs of training to be compliant with licensing
- necessity for high levels of training for certain procedures.

As most stakeholders stated a preference for the oversight models presented, the submissions were assessed for the level of support for each of the options provided in the Consultation RIS. In addition, some further assessment was performed regarding the level of support for education level, grandfathering, concerns and impacts, and equipment/premises requirements.

This review indicated that while there was a high level of support for Option 3 from the medical practitioners, there was a similar combined response rate supporting a modified version of Option 3 and those expressly not supporting Option 3 or indicating support for Option 2. From this information, it was inferred that the majority of stakeholders were in favour of some form of oversight for the industry.

Aside from the information gained in the preference for a way forward, no significant additional data was received regarding injuries, business implications or health outcomes from any of the options presented. Therefore, there was insufficient evidence to support a justification to adopt or implement any of the options outlined in the Consultation RIS for oversight of the industry.

It was decided by the RHC that a positive step to contributing to safety in the delivery of these services would be to engage an expert group to publish guidance material. The guidance material would be accompanied by fact sheets, brochures and frequently asked questions aimed at informing the Australian public about risks and potential health implications of undergoing laser and IPL based cosmetic therapy. The adoption of this guidance material would provide a means by which services could measure their safety performance against good practice.

6. References

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