

6th December 2021

**Environmental Health Standing Committee** 

RadiationPolicy@health.gov.au

#### **Re: National Strategy for Radiation Safety**

The Australian Society of Dermal Clinicians (ASDC) is writing to provide our views in relation to the National Strategy for Radiation Safety and implementation plan. As a professional body representing allied health professionals, educators, researchers, and industry associates, we support the proposed national strategy to provide uniformity to radiation safety regulations and guidance.

As an industry body representing professional skin health practitioners that provide health services, our members are directly impacted by this proposed national framework for radiation safety and regulation. Our feedback relates to cosmetic and therapeutic (health) services using **non-ionising radiation** apparatus, including intense light and LASER apparatus. As an industry organisation, we advocate for safety and standards of care for consumers receiving skin therapies and the provision of therapy utilising an evidence-based approach.

As the peak professional body for Dermal Clinicians and Therapists, we have identified areas within the national strategy related to cosmetic LASER and Intense light sources that impact our profession. We want to highlight and respond to these impacts in the hopes that these recommendations and points can be further considered before further stakeholder engagement and implementation.

Some of these are outside the scope of the consultation paper provided. We believe that during this time, it is reasonable to raise concerns relating to the national strategy that impact our members and to raise further awareness of the scope of practice of Dermal Clinicians and Therapists providing cosmetic and health services using **non-ionising** light-based and LASER techniques. We have also included in our discussion of the national strategy considerations and support for uniformity, science-driven policy and future-proofing of any regulation relating to the regulation of radiation safety that is relevant to the use of non-ionising radiation apparatus for the use of cosmetic and therapeutic devices.

## Non-Ionising radiation regulation: Light and LASER apparatus cosmetic or therapeutic devices?

The ASDC would like to highlight that for public safety, we feel very strongly that it is essential for this regulation to capture the provision of therapy using non-ionising light and LASER apparatus for **both services** marketed as 'cosmetic' and 'therapeutic' in purpose.

LASER and Intense light treatments can alter cellular processes and lead to changes within skin structure and/or function with the potential to cause injury and harm. In many cases, the apparatus used in 'cosmetic' and 'therapeutic' applications are the same and includes risks and complications associated with the treatment. It does not seem logical to separate these into cosmetic or therapeutic uses. Or for one aspect of the sector to be regulated, while the other to not.

For the majority of Australians, non-ionising radiation procedures, including LASER and intense light treatments, are considered 'for cosmetic purposes'. These techniques are also used to correct dysfunction, disorder and disease of the skin. The ASDC takes the standpoint that all techniques, due to the impact on cellular responses and resulting tissue changes with these technologies, are therapeutic and must be considered health services. This is regardless of whether it addresses a 'cosmetic' concern of appearance or a diagnosed medical condition. Therefore in our opinion, these therapies and services no longer act superficially on the skin, nor are the effects solely cosmetic, temporary and completely reversible.

Currently, regulatory bodies view many light and LASER treatments as cosmetic procedures; however, these services are associated with greater risk due to their mechanism/s to cause side effects and adverse events that may also be more significant and long term. Therefore, these services and associated apparatus should be held to standards and regulated because they are a risk to public safety.

Another consideration is that **many energy apparatus** used in the cosmetic medical/beauty sector may not be sufficiently covered by regulation proposed in the national strategy. Or in any current regulatory frameworks in Australia that focus on LASER and intense light sources. These energy devices can use electromagnetic, ultrasound and radiofrequency wavelengths.

The cosmetic medical & beauty sector is a largely unregulated, billion-dollar industry with no uniformity between states or approaches to practitioners using these apparatus (Cosmetic Physicians College of Australasia, 2016). Without uniformity in regulation, there is a significant risk to public safety.

# About Dermal Clinicians: Providers of Cosmetic and Health Services using Non-Ionising Radiation Sources

<u>The Australian Society of Dermal Clinicians is an affiliate member of Allied Health Professions</u>

<u>Australia (AHPA).</u> We are a professional body representing an emerging allied health profession operating within an evidence-based paradigm.

Dermal Clinicians are allied health professionals with an AQF 7 Bachelor of Health Science with expertise in the assessment and management of the skin in health and disease. **As part of** their Bachelor Degree programs, Dermal Clinicians are robustly educated and trained in the scientific theory and evidence-based application of non-ionising light and LASER techniques for skin-related

applications. This includes many hours of supervised clinical practice. Dermal Clinicians with an AQF 7 qualification can provide therapeutic management of concerns relating to skin health and appearance and common skin conditions, disorders and diseases that affect the Australian population.

Dermal Clinicians are independent allied health practitioners. However, they often work collaboratively with GP's, Skin Cancer Medical Practitioners, Dermatologists, Cosmetic Physicians, Plastic Surgeons and Vascular Surgeons, among others. Dermal Clinicians can provide independently (within their scope of practice) therapeutic management of the skin using non-ionising light and LASER apparatus. In some instances, medical professionals will delegate therapeutic interventions to Dermal Clinicians due to their theoretical and practical expertise in providing Light and LASER procedures.

For more information on the education and training of Dermal Clinicians in the Bachelor Degree programs, you can refer to **Appendix 1 - ASDC Education Partners**.

#### Case for uniformity of regulatory frameworks and requirements.

The cosmetic health services sector is growing, and providers of services within this sector are diverse, including non-medical and medical professionals, unregistered and registered, self-regulated and APHRA regulated. Therefore, the ASDC believes that the national regulation should have uniformity in the minimum standards of competency, educational requirements, and limitations to the scope of practice through licencing that allows all practitioners to provide these services when requirements are sufficiently demonstrated anywhere in Australia. This would then have flow-on effects to minimum standards for accreditation of education and training and potential for some restrictions to the purchase of non-ionising light and LASER sources.

## CASE 1 - Regulation, too little, too much?

<u>Currently, in Australia, only three (3) states</u>, including Western Australia, Queensland, and Tasmania, regulate the use of non-ionising LASER apparatus and users for cosmetic/medical purposes.

Tasmania is the only state that regulates the use of intense light sources (non-ionising radiation).

Each of these states has different requirements for users and premises to provide services using these apparatus. These differences have financial and career implications, particularly if moving from one state to another or operating nationally.

Example 1 – Practitioners, licencing and scope of practice.

Full members of the Australian Society of Dermal Clinicians are allied health professionals with AQF 7 Bachelor Degree qualifications. As part of their undergraduate degree they receive training in the theory and practice of a range of LASER and light-based procedures. These professionals are recognised by the Australian Society of Dermal Clinicians to use the professional title of 'Dermal Clinician'. As an example of the inconsistency that our members experience with current regulation around Australia, one of the procedures performed by Dermal Clinicians during scar management is Ablative Class IV LASER techniques. This involves the removal of the upper layers of the skin to initiate a wound healing response and re-organisation of the scar during repair.

In Western Australia, this procedure, like all LASER and IPL procedures, can only be performed by Medical Practitioners. In Queensland, our members have informed us that it can be unclear whether they can use these apparatus independently. Even though these procedures are within their university training, members often still need to undertake numerous hours of supervised practice before being issued with a user licence. Further, even with user licences, it's not clear that treatments are authorised to be provided by Dermal Clinicians unless treatments have been delegated within a medical practice under the supervision of a medical practitioner. While in most other states, a Dermal Clinician can provide this procedure as part of their scope of practice. This scope of practice being determined by their education and training in LASER theory and practice, work occupational health and safety, infection control and wound management.

Table 1. Details Australian state and territory licensing and required qualifications for the operating of laser and IPL devices (As of OCT 2021) (Leow, 2017 & ARPANSA, 2015).

State/Territory	Laser Licencing	IPL Licencing	Qualifications
Western Australia	Registered medical practitioners only	Not required	A person operating a Class 3B or Class 4 lasers must have appropriate qualifications and experience.  Medical practitioners may work under a licensee where the licensee is present on the premises.
Queensland	Required	Not required	Requires a licence to use a Class 4 laser for medical and/or cosmetic purposes
Tasmania	Required	Required	Requires a certificate of compliance.  Operators must 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.
South Australia, Victoria, New South Wales, Northern Territory, Australian Capital Territory	Not required	Not required	N/A

(Image Rich et al., 2021)

Example 2 – Public safety, education & training devices.

There is almost no minimum standard for who can purchase or use a LASER or intense light apparatus in some states. Apart from requiring a LASER safety certificate which can in some cases be done in as little as a few hours. In these states there is no regulation to inhibit any lay person buying a device whether it be from a reputable medical aesthetic device company or from the internet.

At this point in time, a great deal of the danger to the public is associated with providers of LASER and intense light procedures working outside their scope of practice. This is due to insufficient education and training to understand the risks or adapt to individual therapeutic needs with an understanding of patient factors that can impact on treatment. The ASDC's position is that sufficient

education and training must be provided to know how to perform the treatment and have adequate depth of understanding of the tissue effects and responses to identify, prevent, and manage common complications associated with providing these services. Currently, this requirement is significantly lacking, with providers being able to purchase a device online, train with video or weekend courses and provide therapies to the public the next day. This includes laypeople from butchers all the way through to medical professionals.

The ASDC represents allied health professionals and industry members of the sector with specific education and training in the science, tissue responses, including injury and repair, provision of nonionising radiation therapies in a wide variety of applications, and robust education and expertise in prevention and management of common complications. It concerns the profession greatly that at the current time scope of practice isn't limited or relevant to an individuals education and development of sufficient experience to work safely with the public. This concern also extends to the accessibility to purchase these devices by untrained individuals with no requirement to demonstrate adequate education and experience to operate them.

#### Case for science-driven policy

Despite numerous media reports of adverse events associated with LASER and Intense light procedures as well as industry-wide expression for the need for increased oversight of regulatory processes, the sector is still largely unregulated.

Serious harm can and does result, indicating a risk to public safety when not used correctly. Serious harm includes potential risks for eye damage, skin damage including scarring, the inappropriate treatment of skin conditions that can result in problems with the diagnosis of serious underlying medical conditions such as skin cancer as well as work occupational health and safety risks such as inhalation of plume (Town & Godfrey, 2021; ICNIRP, 2020; Qutob et al., 2019).

In 2015, ARPANSA provided the results of a study that investigated causes of injury in the cosmetic use of LASER and IPL. In this study, 430 LASER operators that were both medical and non-medical were surveyed anonymously over a 12 month period. This study found that 416 burns or permanent scarring incidents were reported, and 268 cases were rated as severe. It was reported that most injuries were related to insufficient training and education.

ARPANSA also released the Consultation Regulatory Impact Statement (RIS) in the use of Intense Pulsed Light (IPLs) Sources and Lasers for Cosmetic or Beauty Therapy for public consultation. After reviewing over 241 stakeholder submissions, it was determined that there was insufficient qualitative evidence to support cost versus the benefit of uniformity and increased regulation at that time (ARPANSA, 2015).

Currently, only the regulated states in Australia require mandatory reporting of incidents related to the use of LASER apparatus, whether they be mild, moderate or severe. In Western Australia, these incidents are only reported by medical practitioners as they are licenced to operate the LASER apparatus. While each state's health commissioner or ombudsman does receive complaints regarding providers of health services, including LASER and Intense light sources, it is not mandatory or even well-advertised within the beauty/cosmetic sector or to the public. This is mainly a resource for mediation of complaints related to health complaints law rather than a register of events.

Therefore this leaves a large body of data missing from the current picture to inform regulation discussions.

## Science driven policy to ensure public/practitioner safety

The ASDC supports that any policy and regulation should be driven by scientific inquiry and supported by evidence. As such, the ASDC commissioned two research studies with Victoria University Melbourne. The first to investigate the prevalence of adverse events, why data on this is currently lacking and what should be done to rectify this. The second to explore the knowledge of PPE and health risks associated with performing LASER and IPL procedures such as exposure to plume.

The results of the pilot studies and the first 12 months data are currently in pre-publication for the ASDC. However, we present some of the findings of these projects.

Rich et al. (2021) surveyed 47 incidences of LASER/IPL injury. Participants were those that received an injury. The study then evaluated the type of injury, the severity, the provider's education, who the incident was reported to, and the participant's satisfaction with the outcome.

- This study found that **91.49% of the incidents were not reported** formally either to the clinic or practitioner that provided the service or to any other professional body or health complaints department. 4.26% reported the event to consumer affairs, 2.13% reported to the health commissioner and 2.13% to their insurance company. Rich et al. (2021) recommended an incident reporting system similar to the TGA Adverse Event Management System that gathers information on events associated with medicine, whether complementary, over the counter or prescription. For the purposes of monitoring safety, the consumer is contacted by representatives if further details are required and to discuss the events and identify if these events are recurring.
- Due to the small sample size, the study could not determine whether qualification impacted the incidence of adverse events; however, **26.5% of the participants did state that they were unsure of the operator's qualifications**. This demonstrates a gap in standardising requirements for training and education and the legal obligation to state these qualifications to consumers prior to the provision of services.
- Of the 47 participants surveyed, 28 adverse events were related to hair removal procedures. This is expected as it is one of the most performed procedures using LASER and IPL apparatus (Thomas & Houreld, 2019).

Through thematic analysis, McCall et al. (2021) surveyed 15 participants and evaluated participants' experience concerning their use of PPE with LASER and IPL and their knowledge of the health risks associated with plume that is a by-product of some LASER and IPL procedures.

The study reported that of the 15 participants, seven had experienced adverse health effects
related to the plume. This included coughing, swelling, burning around the eyes, blurred
vision, exacerbation of asthma symptoms and one participant reported acquiring asthma
while performing plume producing procedures. Those that worked long days performing
plume producing procedures reported a higher impact of side effects.

Barriers were identified that inhibited protecting practitioners from the occupational health
risk of plume including: lack of standardised training in occupational health and safety that
also covers the health risks and minimisation strategies for performing LASER and IPL
procedures, lack of regulation regarding the design of premises to ensure adequate airflow
and filtration for plume, lack of regulation regarding the supply of PPE by the business and
use of PPE by practitioners such as N95 masks.

## Case for future proofing regulation

In a <u>parliamentary briefing</u>, it has been reported that health professionals continue to be in short supply, with many being added to the immigration skilled occupations list. It has been estimated that there will be a shortage of 100,000 nurses by 2025. With the health problems facing Australia in the years to come, allied health is going to play a more significant role in preventative health and management of common conditions related to their scope.

Dermal Clinicians play an essential role in the early detection of skin disease and disorder, assisting Australians to age well and healthily. Dermal Clinicians can manage common skin conditions to prevent further deterioration and subsequently assist with improving mental health related to the burden of skin disease and disorder. The government has a <u>10-year reform plan</u> integrating allied health and medical health services.

Leow (2017) reports in their article 'Navigating the disparate Australian regulatory minefield of cosmetic therapy' that in reviewing medical literature there is 'a lack of evidence to suggest that non-medical practitioners are less knowledgeable or skilful in performing these (LASER/IPL) treatments'. It was also discussed that most medical professionals receive no undergraduate or postgraduate training in the use of LASER and IPL devices. Even dermatologists may have the theoretical knowledge but may not have the practical ability to operate devices effectively. It was noted in this article that non-medical university-trained Dermal Clinicians had a comparable if not higher level of knowledge and skills than specialty-trained Dermatologists.

This information highlights that any regulation must be written to adapt to future health concerns and be responsive and inclusive to the changing health workforce, including emerging allied health and health professions.

#### ASDC proposed considerations for regulation

The Australian Society of Dermal Clinicians understand that national standards for radiation safety will take time and consultation to implement. Particularly to ensure that it is uniform, evidence based, inclusive and is able to adapt to future requirements. As part of our feedback, we have surveyed our members. We have prioritised what we believe will help ensure that regulation is science-driven and responsive to the needs of public safety and economic considerations in the regulation of non-ionising radiation for cosmetic/therapeutic applications.

 Creation of a centralised register for reporting of incidents and adverse events to gather data on the risk associated with these procedures. At this time, the information is anecdotal. Development of guidance involves understanding the degree of risk, specific areas of risk, and prevalence to provide adequate support to those providing these services and the public seeking information. This register could be modelled on the TGA system.

- 2. While outside of the scope of this discussion, this may require the establishment of a separate advisory committee or council composed of professional bodies representing practitioners using non-ionising radiation to provide feedback. Examples of these stakeholders would include the Australian Society of Dermal Clinicians (ASDC), Cosmetic Nurses Associations (CNA), Australasian Dermatology Nurses Association (ADNA), Aesthetic Practitioners Advisory Network (APAN), Aesthetic Beauty Industry Council (ABIC) as well as medical professional bodies for Cosmetic Physicians (CPSA) and Cosmetic Dermatologists (ASCD)
- 3. Procedures/apparatus should be rated for risk based on the potential for harm and/or long-lasting effects. Competencies should be mapped based on this risk assessment. For example, Ablative LASER techniques that remove the entire epidermis require training in basic infection control and asepsis, wound management, safe operation of the device, and provision of the therapeutic procedure, including prevention and management of commonly associated complications.
- 4. Educational requirements to be mapped to these competencies and accreditation of programs to assure that they are sufficiently robust to meet competencies. This can offer pathways to education and training to ensure that all sector members have opportunities to meet competency requirements if upskilling is required or are entering with different professional attributes of knowledge and skill.
- 5. Licensing based on competency and education level that limits the scope of practice. This would provide mechanisms to ensure safety to the public as although you may have a device that can perform multiple functions, you can use what your education, training and experience dictates is within your scope of practice.
- 6. The sale of equipment needs to consider licencing and scope of practice.

In summary, the ASDC advocates for safety and standards of care for consumers receiving skin therapies and the provision of therapy with an evidence-based approach. As an emerging allied health profession, highly skilled in the area of LASER and Intense light procedures, we are supporting a national standard for radiation safety. We trust that you will consider the above feedback to develop the national standard and its implementation further. We would welcome and be glad to provide further information should you require it during the further stakeholder consultation.

Kind regards

Jennifer Byrne

Chairperson of the Australian Society of Dermal Clinicians.

#### **Appendix 1 - ASDC Education Partners**

Victoria University (Melbourne) - Bachelor of Dermal Science

<u>Victoria University Dermal Clinic</u> - please review procedures performed as part of supervised clinical practice.

Australasian College of Health and Wellness - <u>Bachelor of Applied Health Science (Clinical Aesthetics)</u>

Australian Dermal Science Institute – Bachelor of Applied Health Science (Clinical Aesthetics)

Torrens University - Bachelor of Health Science (Aesthetics)

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