

REGULATORY IMPACT STATEMENT

Radiation Amendment (Tanning Units and Fees) Regulations 2008

September 2008

This Regulatory Impact Statement has been prepared in accordance with the requirements of the Subordinate Legislation Act 1994. Its purpose is to inform interested parties regarding a proposal to make new regulations. Comments are invited and should be addressed to the contacts listed at Appendix 2 by 28 days from the date of release.

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Summary

The proposed Radiation Amendment (Tanning Units and Fees) Regulations 2008 are intended to replace the current Radiation (Tanning Units Amendment) Interim Regulations 2007. These interim regulations were made as an urgent response to rapidly increasing concerns over the health impacts of rising solarium use, in the context of a rapid expansion of the industry. The proposed regulations will have the effect of extending the recently introduced regulatory scheme in relation to solarium businesses for a period of 10 years. In addition, the proposed regulations will strengthen the existing regulatory requirements by effectively prohibiting persons under 18 years of age from using solaria.

The regulations effectively declare a tanning unit to be a radiation source for the purposes of the Radiation Act 2005. As a result, operators of solarium businesses are required to have management licences under the Act, while a conditional exemption from the need to obtain a 'use licence' is proposed to be provided in respect of solarium staff. Conditions applied to both the management licence and the exemption from the requirement for a use licence form the mechanism by which the major substantive elements of the regulations are brought into effect.

The major impacts of the introduction of regulations are that they require staff in solarium businesses to:

- refuse access to solaria for persons with type 1 skin (i.e. very fair skin which burns easily and does not tan) and persons under 18 years of age;
- limit client exposures to an appropriate, predetermined level and supervise these exposures;
- obtain informed consent based on the provision of information concerning the risks of using solaria;
- provide protective goggles.

Promotional material is also required to refrain from stating or implying that the use of solaria is without risk.

The proposed regulations are expected to reduce solarium use by approximately 50%. This is expected to reduce the incidence of solarium related skin cancer by significantly more than 50%, largely as a result of the prohibition on solarium use by particularly vulnerable groups. Between nine and 12 deaths from melanoma are expected to be prevented over 10 years, while the overall benefit of the regulations is estimated at between \$25.0 million and \$56.6 million in present value terms. By comparison, expected licensing costs amount to only \$1.25 million. Solarium businesses are expected to incur a loss of revenue of up to \$48.0 million over 10 years in present value terms. However, this cost must be

regarded as a transfer in economic terms, rather than a real economic cost attributable to the regulations. This reflects the fact that this loss of revenue will be balanced by increased consumer spending in other areas.

Two alternatives to the proposed regulations have been assessed. The first differs from the proposed regulations in also requiring that use licences be obtained by all solarium employees. It is considered likely that this approach may yield some small additional benefits in terms of improved compliance with the requirements of the regulations. However, overall licensing costs would be substantially greater, being estimated at up to \$9.0 million in present value terms over 10 years. As a result, this alternative is considered to be most likely to generate a lower NPV than the proposed regulations as well as having a significantly smaller benefit/cost ratio.

The second alternative considered differs from the proposed regulations in allowing 16 and 17-year-olds to use solaria, subject to written parental permission being obtained. This alternative has the advantage of allowing parents to make choices in relation to their children's health. However, it is inconsistent with both the consultation draft of the revised Australian Standard and the draft amendment No. 5 to the National Directory for Radiation Protection, both of which were recently released for public consultation. Should the NDRP amendment be approved, Victoria will be obliged to implement its provisions under the terms of the relevant national uniformity agreement. Hence, this alternative is unlikely to be feasible.

Moreover, this reflects the fact that young people constitute one of the most vulnerable groups in terms of skin cancers being developed as a result of solarium exposure and the fact that this alternative would, with little doubt, be substantially less effective in reducing the incidence of skin cancer resulting from this course.

The proposed regulations and the identified alternatives were assessed formally using a multi-criteria analysis, the criteria assessed being minimising regulatory costs, maximising regulatory benefits, consistency with national agreements and protection of vulnerable groups. The proposed regulations scored most highly, followed by the alternative of regulating with a two-tiered licensing scheme. Consequently, it is proposed to proceed with the proposed regulations.

The solarium industry was consulted prior to the introduction of the current interim regulations and has been generally supportive of the adoption of a regulatory approach, given the prior failure of efforts to increase voluntary compliance with the Australian Standard. Feedback received since the implementation of the interim regulations indicates that industry continues to be broadly supportive of the current arrangements.

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1. Nature and extent of the problem

1.1. Overview

In recent decades in Australia there has been a substantial increase in the level of awareness of the problem of skin cancer and the need to act to reduce the incidence of skin cancers. Australia has among the highest skin cancer rates in the world¹ and substantial public policy action has been taken in recent times with a view to reducing the incidence of skin cancer and its associated health and financial costs.

The single major risk factor in relation to skin cancer is exposure to ultraviolet radiation. The great majority of this exposure necessarily derives from exposure to sunlight. However, there is now also a significant and accumulating body of evidence demonstrating that exposure to ultraviolet radiation in the context of solarium use is an important contributor to skin cancer risk. Gordon et al (2007)² reported that:

Results from a meta-analysis of 21 studies investigating the association between solarium use and risk of skin cancer show an increased risk for developing melanoma (by 22%) and squamous cell carcinoma (by 78%), an increased risk of melanoma for first users under 35 years (by 98%) and for women (by 71%). (pp 3-4).

Box 1: Defining sunbeds

Gordon (2007) defines sunbeds (or tanning lamps) as being “*devices that emit artificial ultraviolet radiation. Individuals expose their skin to the radiation for the purpose of inducing a tan while indoors for cosmetic reasons*”.

The finding of an increased risk of melanoma due to sunbed use was found to be statistically significant: the mean increase in risk for those who had ever used a sunbed was increased by 22%, while the 95% confidence interval was between a

¹ Specifically, Australia has the highest rate of Melanoma, the most deadly skin cancer, among males and the second highest rate among females. See: *Australia's Health 2004*. Australian Institute of Health and Welfare.

² Gordon L & Hirst N. (2007). *The health effects of using solarium and potential cost-effectiveness of enforcing solarium regulations in Australia*. Queensland Institute of Medical Research, November 2007.

7% and 39% increased risk. That is, there is a 95% probability that an increase in melanoma risk within this range is incurred due to sunbed use.

Moreover, while

... individuals who have ever used a solarium have a 22% increased risk of developing melanoma. When the analyses were confined to studies which adjusted for other possible explanations for increased numbers of melanomas (skin cancer history, outdoor exposure behaviours, age etc) the associated risk was even greater at 1.36. (pp 32-3).

That is, on the best available measure, persons who use sunbeds increase their risk of developing melanoma by more than one third. Gordon *et al* also found that the use of solaria increases the risk of developing Squamous Cell Carcinoma (SCC) by 78%, although it does not appear to increase the risk of developing Basal Cell Carcinoma (BCC).

The above quote from Gordon cites particularly large increases in melanoma risk for those who first use sunbeds when under 35 years of age. Other research indicates that exposure to ultraviolet light during adolescence is strongly associated with later development of melanoma. For example, Autier (2008)³ states that

“A considerable body of experimental and epidemiological data supports the hypotheses that childhood and adolescence are the key periods of life for the initiation of the mechanism involved in the genesis of adult melanoma”.

This clearly indicates that adolescents using sunbeds can be expected to be at very high risk. Work by Veierod *et al* (2003)⁴ specifically estimates the increased melanoma risk due to childhood and adolescent sunbed exposure. Veierod studied 106,379 females in Sweden and Norway between 1991-1999 and found exposure to sunbeds of greater than or equal to one month between the ages of 10-19 was associated with an increased melanoma risk of 52% (95% CI (0.56-4.12)).

At the same time as evidence about the extent of the hazard posed by solarium use has been accumulating, the extent of solarium use in the Victorian and Australian population has been growing rapidly. According to Makin *et al* (2007)⁵

³ Autier, P. (2008), “Artificial ultraviolet sources and skin cancers: rationale for restricting access to sunbed use before 18 years of age”, *National Clinical Practice Oncology*, April 2008, vol. 5, no. 4, p. 178-179.

⁴ Veierod MB, Weiderpass E, Thorn M, *et al*. A prospective study of pigmentation, sun exposure, and risk of cutaneous malignant melanoma in women. *J Natl Cancer Inst* 2003;95:1530–8.

⁵ Makin JK, Dobbinson SJ & Herd NL. (2007) *The Increase in Solariums in Australia 1992 – 2006*. Australian and New Zealand Journal of Public Health Vol 31., No. 2, pp 191-192. Data on solarium numbers based on Yellow Pages listings.

there has been a 300% increase in the number of solarium operating in Australia's capital cities in the decade to 2006, with Melbourne experiencing a much larger than average 500% increase over this period. Melbourne was found to have more solarium in operation than any other capital city in 2006, with numbers being approximately three times those of Sydney.

Other sources suggest that the rate of increase in the number of solarium operating in Victoria may be even greater than that estimated by Makin. For example, the 2004 Cancer Council of Victoria/SunSmart report on compliance with the Australian Standard by solarium found that the number of solarium businesses identified had increased from 23 in 1997 to 143 in 2004 – an increase of over 520% in only seven years.

The above estimates are based on non-exhaustive counts of solarium, using sources such as Yellow Pages listings. Thus, while they may provide reasonable estimates of the growth in solarium numbers, they will necessarily substantially underestimate total numbers of solarium.

DHS conducted a census of solarium businesses operating in Victoria in 2007 and found that tanning units were operating at 436 sites. As at May 2008, this number had fallen to 308 sites, a 30% reduction. These sites were operated by a total of 272 businesses and used 828 individual tanning units. As these numbers indicate, there has been an approximate 30% reduction in solarium numbers over the last 12 months. However, this reduction has followed substantial publicity regarding the dangers of solarium use and may prove to constitute a short term reversal in the longer-term trend of increasing solarium use if the regulatory arrangements adopted on an interim basis in 2007 are not continued in force.

Risk levels

A standard definition of risk is as follows:

$$\text{Risk} = \text{hazard} \times \text{exposure}$$

In these terms, the fact that the level of exposure of the Victorian and Australian population is increasing rapidly implies that the total risk to the population posed by solarium use is also increasing rapidly.

Moreover, comparative international data suggest that there is a significant probability that the extent of exposure to solarium use may increase much further. Dobbins *et al* (2006) reported rates of solarium use for female adolescents of up to 70% in Sweden and between 37% and 42% in the United States, whereas Gordon (2007) reports that only 12% of NSW school children were found to have used solarium in a recent survey. Moreover, this figure is

substantially higher than the 3% of Victorian adults who reported having used a solarium in the previous 12 months in 2004. These data suggest that solarium use in the general population is highly likely to continue to increase, assuming that younger users continue to use solariums over time.

The fact that current rates of solarium use in Victoria appear to be substantially lower than those experienced in the United States and some European countries also suggests the possibility of further increases in solarium use. This would necessarily result in increased population exposure to the harms associated with solarium use, particularly when considered in the context of the recent trend toward rapidly increasing numbers of solariums in Victoria and some direct evidence of rapid increases in the proportion of the population using solariums⁶.

Market failure issues

Gordon (2007) argues that the solarium industry is characterised by market failures, particularly arising from information asymmetries. In particular, marketing activities undertaken by the industry have promoted solariums as offering health benefits, while the risks of solarium use have gone largely unacknowledged. While the relevant Australian Standard (*Australian Standard AS/NZS 2635:2002 Solariums for Cosmetic Purposes*) requires information about cancer risks arising from the use of solariums to be provided to intending users, the standard has only voluntary status. The most recent survey based evidence (see below) finds that such information is provided in less than 50% of cases and that the provision of this information has declined over time. This provides a strong indication that the non-regulatory efforts undertaken to date to correct market failure due to information asymmetries have had only limited success.

A second issue arises from the generally youthful age profile of solarium users. The Australian standard currently requires that parental consent be given before those under 18 years of age can use a solarium. However, survey data show that compliance with this requirement currently also stands at below 50%. Persons under 18 years of age are acknowledged to be relatively ill-equipped to make rational choices in their own interests in many circumstances. This can also be considered to be an issue of market failure.

Section 1.3., below, provides further information on the development and adoption of the Australian standard as a non-regulatory means of addressing these market failure issues, together with other major risk factors in relation to solarium use and highlights the limited effectiveness of this non-regulatory approach.

⁶ A 2001 "SunSmart" survey found that only 1.5% of Victorians used sunbeds. Hence, Dobbins's 3% figure suggests a doubling of this rate in only 5 years.

1.2. Estimates of the current health costs of solarium use

Recent research has attempted to estimate the extent of the impact of solarium use in increasing overall population exposures to ultraviolet radiation. In particular, Diffey (2003)⁷ developed a model to estimate the impact of artificial UV radiation on melanoma rates. Diffey estimated that solarium use accounts for between 3% and 12% of total exposure to ultraviolet radiation for the British population. Using the midpoint of this range (7.5%) and citing estimates that 80% of melanomas result from exposure to ultraviolet radiation, Diffey estimates that 6% of all melanomas in the British context can be attributed to the use of solarium⁸.

Diffey's model has been adopted, with variations, by Gordon *et al* (2007) to develop estimates of the contribution of artificial UV radiation to melanoma and Squamous Cell Carcinoma (SCC) rates⁹ in the Australian context. Gordon concludes that the contribution of sunbed use to melanoma is much smaller in Australia than in the UK, for two major reasons:

- **Greater natural UV exposure.** The average intensity of UV radiation in Australia is extremely high by world standards and is more than an order of magnitude higher than in the United Kingdom. Thus, notwithstanding the fact that a far smaller portion of the population engages in outdoor sunbathing in Australia, the overall population dosage due to "natural" UV exposure is substantially higher in Australia than in the UK.
- **Lower sunbed usage.** Gordon reports that the proportion of the Australian population using sunbeds is substantially lower than that in the UK and that the intensity of solarium usage by this group in Australia is also significantly lower than in the UK¹⁰. Therefore, total population exposure to UV radiation from artificial sources is substantially lower in Australia than in the UK.

Given the combination of these two effects, Gordon estimates that the contribution of sunbed usage to total melanoma incidence in Australia is 0.4% (range 0.2% to 0.8%)¹¹. Gordon's calculations suggest that the relative

⁷ A quantitative estimate of melanoma mortality from ultraviolet A sunbed use in the UK. *British Journal of Dermatology*, Vol. 149, pp 578-581 (2003).

⁸ This estimate may overstate the role of solarium to some extent, as there is evidence to suggest that sunburn constitutes a specific risk factor for the development of melanoma, while burning does not generally occur as a consequence of sunbed exposure.

⁹ Research indicates that exposure to UV radiation does not affect risk levels for Basal Cell Carcinoma, the other major category of skin cancer.

¹⁰ Gordon's model is based on an estimated mean number of sunbed sessions of 10 per year per user.

¹¹ This estimate and, by implication, the following estimates of numbers of deaths, was derived through modelling using the Monte Carlo statistical method.

contribution of sunbed exposure to total melanoma incidence in Australia is only approximately 1/15 of that in the UK¹².

Nonetheless, Gordon estimates that four melanoma deaths per year (range 1 – 7 deaths) and 34 new cases of melanoma per year (range 12 – 62 cases) in Australia are caused by sunbed exposure¹³. Using a similarly specified model, Gordon also estimates the impact of sunbed exposure on SCC cases.

1.3. Specific problems associated with the use of solaria

A number of factors influence the degree of risk associated with solarium use. Recognition of risk and responsibility issues has led, over time, to the development of an Australian Standard to guide industry practice. This is *Australian Standard AS/NZS 2635:2002 Solaria for Cosmetic Purposes*. Key elements of the Standard include the following:

- **Information provision:** information about the cancer risk associated with solarium use should be provided to all clients and potential clients.
- **Protective goggles:** protective goggles should be provided at all times to minimise the risk of eye injury due to solarium use.
- **Skin type:** Potential users' skin type should be assessed by solarium staff.
- **Prevention of access:** Intending users who are assessed as having fair skin that will not tan (i.e. "Type 1 skin") should not be allowed to use the solarium.
- **Parental consent:** Intending users under 18 years of age should be prohibited from using the solarium unless they have parental consent.

These five key elements of the Australian standard address two distinct types of issues. Firstly, the provisions in relation to protective goggles and skin type/prevention of access aim to reduce health risks to solarium users. The provision of protective goggles serves to protect the eyes, which are particularly vulnerable to damage from ultraviolet radiation exposure. The denial of access to the solarium to persons judged to have fair skin that will not tan ensures that

¹² Diffey's UK estimated range of 3-12% of melanomas caused by sunbed exposure compares with Gordon's range of 0.2 – 0.8%.

¹³ Based on data from the Australian Institute for Health and Welfare (AIHW)(2003), there are 1,146 deaths annually due to melanoma in Australia and 9,524 newly diagnosed cases of Melanoma. More recent data, released after the preparation of Gordon's paper (ABS 3303.0) show that the number of melanoma deaths increased to 1,238 in 2006. Clearly, applying the same methodology to this figure would yield a slightly higher estimate than that reached by Gordon.

those at greatest risk of developing skin cancer from exposure to ultraviolet radiation are prevented from using solarium¹⁴.

Secondly, the provisions in relation to information provision and obtaining parental consent aim to ensure that all users of solarium have effectively provided informed consent before exposing themselves to the risks in question. In the case of users under 18 years of age, the provisions ensure that parents/guardians are aware of, and consent to, their child's exposure.

High rates of compliance with the Australian Standard would be expected to reduce substantially the health costs associated with solarium use. However, the standard currently has only the status of a voluntary code. That is, providers of solarium services are under no legal obligation to comply with the requirements of the standard.

Actual compliance levels have been monitored over a period of time. This monitoring indicates that the level of compliance with the different major requirements of the standard varies substantially, with very low compliance with some of the most important elements being observed. Moreover, there has been little improvement in compliance rates in recent years, as the following data indicates.

Table 1, below, summarises compliance rates with various elements of the Standard, as reported in a 2004 study. Table 1 shows that compliance with the requirement to provide protective goggles is high, with these devices being provided in almost 9 out of 10 cases. The provision of information about the cancer risks of solarium use occurs in about seven out of 10 cases.

However, compliance with the remaining requirements is substantially lower. Potential users' skin type is assessed only slightly more than half of the time, while fair-skinned persons are denied access to the solarium in only about one out of 10 cases. Clearly this latter provision is of paramount importance to the ability of the standard to reduce the health costs of solarium use.

Finally, the standard's requirement to prevent access to the solarium to children under 18 without parental consent is enforced less than half of the time.

Table 1: Compliance of solarium with key elements of the Australian Standard - 2004

| Requirement of standard | Compliance (%) |
|-------------------------|----------------|
|-------------------------|----------------|

¹⁴ Factors making individuals particularly susceptible to developing skin cancers include having type 1 skin, having red hair, having blue eyes and having large numbers of moles on the skin. Age at first use of a solarium is also associated with increased skin cancer risk, although this is likely to be strongly correlated with the extent of overall UV exposure.

| | |
|--|-----|
| Information about cancer risk given | 70% |
| Protective goggles supplied | 87% |
| Skin type assessed | 57% |
| Prevention of access for the fair-skinned | 10% |
| Access without parental consent (under 18s) prohibited | 48% |

Source: *Compliance of inner Melbourne solarium centres with a revised industry standard: access by teens and customers with a sensitive skin type.* Dobbinson, S. & Wakefield, M., Department of Human Services, October 2004.

Table 2 reports the results of a 2006 study into compliance with the standard. In general, it shows relatively little change in the level of compliance with aspects of the standard since the 2004 study. However, in respect of all of the five elements of the standard listed, the direction of change is a negative one; that is, compliance rates have actually fallen.

Table 2: Compliance of solaria with key elements of the Australian Standard - 2006

| Requirement of standard | Compliance (%) |
|--|-----------------------|
| Information about cancer risk given | 47% |
| Protective goggles supplied | 80% |
| Skin type assessed | 50% |
| Prevention of access for the fair-skinned | 7% |
| Access without parental consent (under 18s) prohibited | 45% |

Source: *Solaria Compliance and Evaluation of Public Information Campaign.* The Open Mind Research Group. Department of Human Services, September 2006.

In sum, while the adoption of the provisions contained in the Australian standard by all solarium operators would constitute a relatively effective means of reducing the harms associated with solarium use, experience over a number of years with the implementation of the standard as a voluntary measure shows that it has, at best, been partially effective. Moreover, there was no evidence of any improving compliance trend: rather, the contrary appeared to be the case. Given that this situation of limited compliance with major elements of the standard has persisted, in an environment in which virtually all members of the solarium industry are fully aware of the existence of the standard, it was considered that further action to improve substantially compliance with its provisions was required in order to address effectively the problems identified above. For this reason, the interim regulations were adopted in 2007.

Although the interim regulations came into effect only very recently, some limited information on compliance with the regulations is available. At the time of writing,

DHS had conducted inspections of 42 licence holders, checking for compliance with licence conditions. Only one major instance of non-compliance has been found, involving a coin operated system being operated and the absence of both supervision of the unit and consent forms. The tanning unit was sealed as a result.

In 29 cases, the inspections revealed no compliance problems. Minor compliance issues were found during 12 inspections. These included solaria having their own warning sign displayed instead of the DHS approved warning notice, using their own consent form instead of the approved form set out in the licence condition and some problems with the form of skin type assessment being used.

All of the inspected solaria have claimed to refuse access for persons with skin type 1.

In sum, although the interim regulations have been only recently introduced, there is already evidence to indicate significantly higher compliance rates than had been the case in respect of the voluntary application of the Australian Standard.

2. Statutory authority and objectives of the proposed regulations

The proposed regulations are to be made under the authority of section 139 of the Radiation Act 2005. The objective of the Act is “to protect the health and safety of persons and the environment from the harmful effects of radiation” (Section 1).

Within this context, the objective of the proposed regulations is to protect people, and in particular those at highest risk of skin cancer, from the harmful effects of radiation emitted from tanning units.

3. Outline of the proposed regulations

The proposed regulations are largely similar to the existing Radiation (Tanning Unit Amendment) Interim Regulations 2007. Specifically, the regulations prescribe tanning units to be a non-ionising radiation apparatus for the purposes of the act. The effect of this prescription is to bring tanning units within the ambit of the licensing requirements of the act. The act establishes a licensing system incorporating the following licences:

- **Management licence.** The management licence allows its holder to conduct a radiation practice. Thus, this can be considered to be a business licence.
- **Use licence.** The use licence allows the holder to use a radiation source. Thus, this can be considered to be an operator licence.

The act provides that licences may be made subject to certain conditions. The act also provides that exemptions from the need to obtain a licence may also be provided to a specified group of persons, subject to those persons complying with stated conditions.

In relation to tanning units, there would be an exemption from the need for operators to hold a use licence and would set out a range of conditions to which this exemption was subject. There will also be two sets of conditions established in relation to management licence holders. The first set of conditions relates to a licence to possess a tanning unit and would be applied to operators of solarium. The second set of conditions relate to a licence to sell tanning units.

Conditions of exemption from use licence

The proposed exemption conditions imposed in relation to the exemption from the need for a use licence require solarium staff to:

- prevent access to the solarium by persons under 18 years of age¹⁵;
- prevent access by persons with Type 1 skin (i.e, fair skin which always burns and does not tan),
- ensure that informed consent is obtained, based on an understanding of the risks involved, and
- implement a number of measures aimed at ensuring that the conditions of use are relatively safe.

¹⁵ By contrast, current arrangements allow 16 and 17 year olds to use solarium subject to written parental consent being obtained.

In addition, a written consent form is to be signed, following provision of relevant information. Staff are also required to supervise the user by being within earshot and periodically checking on the user's well-being. This supervision requirement, is intended to reduce the risk of users being exposed to too high a dosage in any one treatment. It was first implemented via the current interim regulations and, *inter alia*, has had the effect of preventing coin operated solaria being used, since DHS does not believe these solaria can be operated in a way that meets the requirement. However, only 6 solarium businesses were using coin operated solaria prior to the adoption of the interim regulations. None of this group applied for licensing under the interim regulations and all have subsequently ceased business.

Users are not to be permitted to use the solarium at intervals of less than 48 hours, while staff are required to determine the maximum exposure period of each user. Where users have not previously used sunbeds, an initial exposure limit is specified. Protective goggles that meet certain specifications are required to be supplied, while promotional material must not claim that solarium use is safe or free from risk. Finally, staff are required to have completed specified training.

The effect of providing an exemption from the use licence provisions of the Act is that, while operators of solarium businesses will be required to hold a management licence, employees of that business will not be required to be licensed. This approach will reduce regulatory costs, while the specification of the various conditions of this exemption, as identified above, will ensure that appropriate control over the behaviour of solarium staff is exercised.

Conditions of management licence in relation to possession

The management licence holder is required to ensure that:

- protective goggles are available,
- warning signs are posted in the premises;
- information is provided to users about exposure limits;
- no claims are made that the use of solaria is free from risk; and
- any replacement tubes fitted to solaria meet the manufacturer's specifications.

In addition, management licence holders have an obligation to ensure that their staff comply with the use licence exemption conditions.

Conditions of management licence in relation to sales and maintenance

A management licence holder engaged in selling and/or maintaining solarium equipment is required to ensure that any tanning unit that they sell complies with the relevant Australian Standard and that it does not emit more than the specified maximum amount of ultraviolet radiation. The licence holder must also ensure that the unit is screened so that all radiation emitted is confined to the area of the unit intended to be occupied by the client.

Purchasers must also be provided with a prescribed warning notice, as well as maximum initial exposure times for persons with different skin types.

4. Expected benefits of the proposed regulations

Box 2: The base case

The base case against which the benefits and costs of the proposed regulations will be measured is the situation which existed immediately prior to the adoption of the current interim regulations. This involves the continued promotion of the Australian Standard to the solarium industry and users as a purely voluntary code.

Given the evidence discussed above to the effect that compliance with the Standard had plateaued prior to the adoption of the interim regulations, it is assumed that the pre-existing compliance rates would remain broadly unchanged in the base case.

4.1. Sources of expected benefits

The proposed regulations are expected to reduce the incidence of melanoma and SCC as a result of solarium exposure in Victoria. They are expected to achieve this effect by reducing the rate of use of solaria and, in particular, by preventing their use by vulnerable elements of the population. The European Union's Scientific Committee on Consumer Products has identified those groups particularly at risk of melanoma as follows:

The important biological risk factors for malignant melanoma are age, sex (in some populations), skin phenotype, moles, freckles and family history.¹⁶

The proposed regulations will address, in particular, the use of solaria by persons in two of these categories: those with the most vulnerable skin type (Type 1) and those under 18 years of age.

Gordon (2007) argues that regulation of the kind proposed in Victoria would be expected to reduce solarium use in three distinct ways:

- Reduction in solarium use due to prohibition on use by persons under 18 years of age;

¹⁶ EU Scientific Committee on Consumer Products (2005) *Preliminary Opinion on Biological Effects of Ultraviolet Radiation Relevant to Health with Particular Reference to Sunbeds for Cosmetic Purposes*. SCCP/0949/05

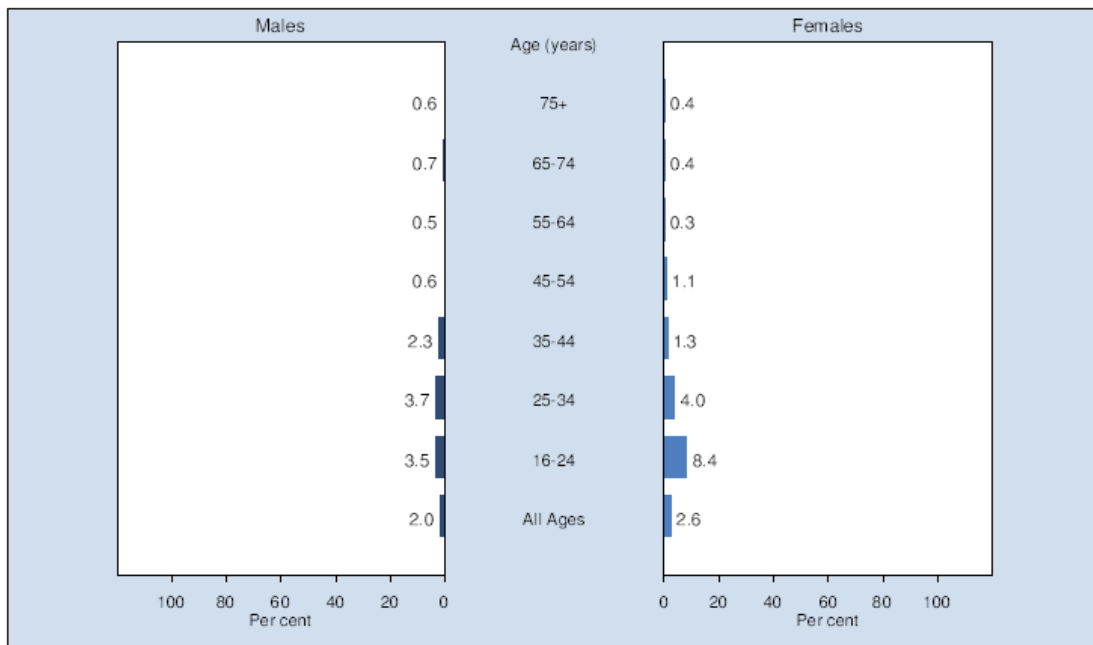
- reduction in solarium use due to prohibition on use by persons with type 1 skin; and
- reduction in solarium use as a result of the combination of the use of warning signs, the banning of promotional material implying that there is no risk from solarium use and the increased use of consent forms.

In addition, the safety of sunbed use will be improved in a number of ways due to the operation of the regulations. In particular, better provision of protective goggles and improved operator control over the length and frequency of exposure will reduce health risks for users.

Reduction in solarium use due to prohibition on persons under 18 years of age

The incidence of solarium use is strongly concentrated within younger age groups. This is demonstrated in the following graph, based on data from New South Wales. The graph presents the results of survey questioning as to whether respondents had used a solarium at any time during the past 12 months, with the proportions answering that they had used a solarium being disaggregated according to age group.

Graph 1: Solarium use in preceding 12 months by age group



Source: Gordon (2007), p 10.

The graph shows that the prevalence of solarium use is far higher among younger age groups, particularly for females. Among females, the 16 to 24 age group is more than three times as likely as the general population to have used a solarium.

The proposed regulations will clearly significantly reduce solarium use among this age group by completely prohibiting use by 16 and 17-year-olds. Use by under-16 year-olds, who fall outside this age group, will also be prohibited by the proposed regulations. However, Gordon suggests that there may be some, partially offsetting, increase in solarium use by 18-year-olds as latent demand, caused by the ban on under 18-year-olds, is satisfied.

The health effects of this impact in prohibiting use by the youngest users are particularly important since, as noted above, there is clear evidence that melanoma risk increases as the age at which a solarium is first used declines. The fact that under-18 year olds are particularly vulnerable to harm from solarium use, combined with concerns over their ability to give informed consent, provides the rationale for moving to prohibit this age group from using solaria under the proposed regulations, in contrast to the position under the current regulations whereby parental consent must be obtained. National regulatory arrangements are expected to harmonise around this standard of prohibition of use of solaria by under-18 year olds in the near future. The World Health Organisation, the Cancer Council and Australian College of Dermatologists also support the ban for under 18 year olds.

Reduction in solarium use due to prohibition on use by persons with type 1 skin

Gordon notes that there is strong evidence of differential skin cancer risk for persons with different physical characteristics. The known risk factors for melanoma include:

- Fair skin that burns easily (i.e., skin type I)
- Green or blue eye colour
- Red hair colour
- Persons with many moles
- Family history of melanoma

Gordon states that having skin type 1 increases melanoma risk by 110 per cent, compared with the general population. Having light-coloured eyes (blue or green) increases risk by 50%. Having red hair increases risk by 260%. Having large numbers of moles on the skin is the largest risk factor, with persons having 101 to 120 moles having a 590% greater melanoma risk than those with fewer than 15 moles. (Gordon (2007), p 23).

Given these factors, and the fact that a number of these risk factors would be cross correlated with having type 1 skin, the prohibition on solarium use by persons with type 1 skin is expected to reduce substantially the melanoma risk faced by solarium users.

Reduced use as a result of the combination of the use of warning signs, regulating promotions and increased use of consent forms.

Melanoma risk will also be reduced somewhat due to the combined effect of these several factors in reducing the overall incidence of solarium use. Gordon argues that the size of this effect is expected to be relatively small. However, it is important to note that the purpose of these measures is to provide greater confidence that solarium use is based upon informed consent.

4.2. Estimating total benefits

4.2.1. Gordon's model

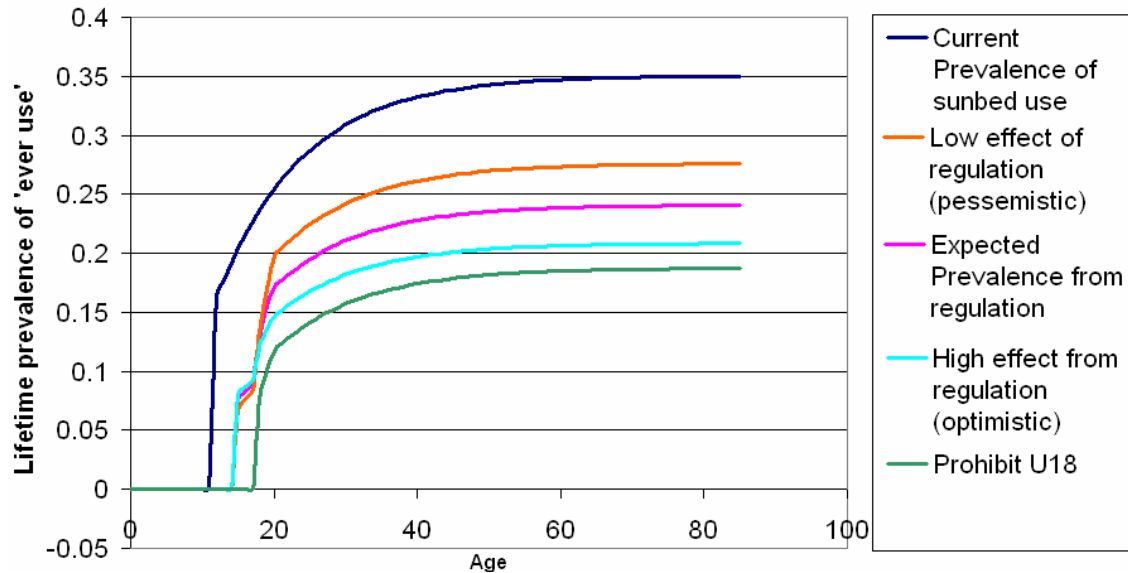
Gordon has modelled the expected total impact of regulations similar to those posed in Victoria. Graph 2, below, summarises these expected impacts. The graph indicates the expected impacts of the regulations on the proportion of the population that will ever use sunbeds, measured against age.

Given that the proposed regulations include a total ban on the use of sunbeds by persons under 18 years of age, the lowest (green) line represents the expected post-regulation incidence of sunbed use. The graph demonstrates that the proportion of the population to have used sunbeds at some point in their life is expected to approximately halve, from 35% to 18% as a result of the impact of the proposed regulations. Specific impacts modelled are:

1. Reduction in sunbed use of 19% due to exclusion of persons with type 1 skin.
2. Reduction of 100% in sunbed use by 15-17 year olds due to regulatory prohibition.
3. Reduction in use of 10% due to increased use of consent forms and other informed consent based factors.
4. Increase in incidence of sunbed use by 18, 19 and 20 year olds of 3%, 2% and 1% respectively¹⁷.

¹⁷ This effect is assumed to exist and is seen as a response to the prohibition on under-18 year olds using solarium.

Graph 2: Impact of regulations on lifetime prevalence of sunbed use



Thus, the expected impact of the proposed regulations includes the exclusion from solariums of a substantial proportion of the population which is at highest risk (i.e. those with type 1 skin), the exclusion of a significant part of the largest user age cohort (i.e. 15-17 year olds) – which is also a group at substantially elevated risk from solarium use – and a reduction in the proportion of the population using solariums due to the various “informed consent” measures.

As the above graph indicates, the combined impact of these measures is expected to be an approximate halving of the proportion of the population using solariums. Moreover, since the reductions in solarium use will be concentrated amongst those at highest risk, it can be expected that the effectiveness of the regulations in reducing skin cancers due to solarium use will be significantly greater than 50%.

Gordon models the expected reductions in skin cancer using the lifetime impact on a specific age cohort. However, this approach is not consistent with that generally adopted in the RIS context, for at least two major reasons.

First, the time horizon involved substantially exceeds the 10 year lifespan of the regulations. This time horizon is problematic since it necessarily assumes the maintenance of the currently proposed regulations into the distant future, a factor which cannot be guaranteed. It is also problematic since the modelling of the costs of the regulations is rendered virtually impossible over such a time horizon.

Second, this approach to analysis effectively ignores the health impact of the regulations on current adults. These impacts are clearly significant, both as a result of the exclusion of persons with type 1 skin and as a result of reduced use due to “informed consent” effects.

4.2.2. Preferred approach

Given the above problems, Gordon’s model has not been used as the basis for benefit estimation in this RIS. Rather, the reduction in harms due to solarium use has been estimated by applying a global estimate of the proportionate reduction in existing harms likely to result from solarium use.

Base case

As noted above, Gordon estimates that, Australia wide, four deaths from melanoma annually are attributable to sunbed use, while 34 new cases of melanoma annually are also estimated to result from sunbed use. These figures are used to generate the “base case” from which expected benefits are calculated.

As Victoria has approximately 25% of the Australian population, this would suggest *a priori* that 1 death from melanoma and 8.5 newly diagnosed cases of melanoma annually would be attributable to sunbed use in Victoria. However, it is likely that the true figures are somewhat greater, since Gordon reports substantial evidence that sunbed use is more widespread in Victoria than in other parts of Australia. For example:

- A 2006 audit of the industry found that the highest growth in sunbed numbers had occurred in Melbourne, with an increase of over 600% since 1992;
- The same audit found that Melbourne had 40% of the total number of solariums identified in all Australian capital cities; and
- Surveys have found that approximately 3% of the Victorian population had used sunbeds in the previous 12 months, compared with 2% of New South Welshpersons and less than 1% of Queenslanders¹⁸.

Thus, it is most likely that Victoria experiences a higher than average incidence of sunbed-related skin cancers. In light of the above, it is estimated that the rate of skin cancers, including deaths from melanoma, attributable to sunbed exposure may be 50% higher than average in Victoria. This would suggest that 1.5 deaths per annum due to melanoma are currently attributable to sunbed use

¹⁸ See Gordon (2007), p 10.

in Victoria, while 12.75 new cases of melanoma annually are due to sunbed use¹⁹.

Given the rapid recent rate of growth in the use of solarium in Australia it is arguable that the base case estimate of solarium related harms should include continuing increases in the currently estimated harms over the next several years. However, recent evidence indicates clearly that following the extensive publicity relating to the connection between solarium use and skin cancer over the past year (commencing with attention to the case of Clare Oliver) the growth in the number of sunbeds available in Victoria has halted, and even been reversed.

While there is inevitably greater uncertainty over the long-term impact of this increase in awareness of health risks associated with solarium use, it seems possible that the rate of solarium use will stabilise over the medium term, even in the absence of regulatory intervention. Given this, the base case is specified in terms of a maintenance of existing rates of solarium use. The impact of adopting this assumption, rather than that of an upward trend in the rate of solarium use, is to introduce a significant measure of conservative bias into the estimation of the expected benefits of the proposed regulations.

Reductions in use due to regulations

The global estimate of reduction in sunbed use can be applied to these estimates of current harms to obtain estimates of the expected benefits of the adoption of the regulations. Specific indicators of the likely impact of the regulations are as follows:

1. Lawler et al (2006)²⁰ found that approximately 19 per cent of solarium users in Queensland had type 1 skin. Assuming the intensity of their solarium use to be average, an effective prohibition on the use of solarium by those with type 1 skin could reduce solarium use by 19 per cent²¹.
2. Graph 1 shows that solarium use is most prevalent among the 16-24 age group. Prohibiting use by 16 and 17 year olds can be expected to reduce overall solarium use substantially.
3. As Graph 2 demonstrates, Gordon's behavioural model assumes that there will also be a long-term impact of preventing solarium use by those under 18 years of age. That is, if prevented from using a sunbed

¹⁹ This estimate effectively implies that 37.5% of solarium related skin cancers currently occur in Victoria. This is broadly consistent with the findings of Makin (2007), who found that Victoria accounted for 41.6% of all solarium businesses identified in Australia in a 2006 survey.

²⁰ Lawler, SP., Kvaskoff, M., DiSipio, T., Whiteman, D., Eakin, E., Aitkin, J. & Fritschi, L. (2006). *Solarium Use in Queensland, Australia*. Australian and New Zealand Journal of Public Health, Vol 30, No. 5, pp 479-482.

²¹ Gordon adopts this estimate in her model.

while adolescents, it is assumed that it is less likely that the habit of sunbed use will be initiated later in life.

4. Gordon also assumes a 10% reduction in sunbed use due to behavioural effects prompted by the combination of greater use of health warnings and bans on positive health messages being disseminated.
5. Graph 2 suggests that the current under-15 age cohort will be almost 50% less likely ever to take up sunbed use if the combination of bans on under-18s and bans on those with type 1 skin are implemented.

The total impact of the above factors cannot be estimated with precision. However, the combination of the 19% reduction in use due to prohibition of use by those with Type 1 skin and a 10% reduction due to behavioural factors yields a 29% estimated reduction in use.

The exclusion of under-18 year olds is also likely to reduce usage substantially. As noted above, a NSW survey found that 12% of schoolchildren had used solarium in the preceding 12 months. This compares with figures cited in Gordon (2007) and reproduced in Graph 1 indicating that usage rates for the 16-24 age group as a whole were only 6%, while usage rates for the remaining age groups were: 25-34 (3.8%), 35-44 (1.8%), 45-54 (0.9%) and older age groups (approximately 0.5%). On this basis, it seems likely that the 16 – 24 age group may account for as many as half of solarium users and that the 16 – 17 year old cohort may account for almost half of the users within this group²².

This should not be taken as suggesting that 20-25% of solarium users are likely to be in the 16-17 age group, however, since the intensity of their solarium use may well be lower than the average. Nonetheless, it is plausible that, say, 10% of solarium users are 16 and 17 year olds.

If under-18 year old users are estimated to comprise 10% of current users, their exclusion would bring the total estimated reduction in use to around 40% in the short term, while the total reduction would be around 45 – 50% in the medium term, due to the behavioural effect Gordon proposes. Another factor which could potentially be relevant would be a possible reduction in the intensity of solarium use by those who continue to use them, due to increasing health concerns prompted by the health warnings and other “informed consent” measures.

Thus, it seems reasonable to suggest that the aggregate impact of the various provisions of the proposed regulations²³ would be to reduce solarium use by half. This estimate implicitly assumes a high level of compliance – i.e. 90+% - with the proposed regulations. While no data are currently available on the rate of

²² i.e. they form around 22% of the age group (2 year cohorts of 9 in total) and have twice the propensity to use solarium of the age group as a whole.

²³ Or, strictly speaking, the licence and licence exemption conditions to be imposed through them.

compliance with the current regulations, due to their very recent introduction, this estimate is based on the fact that the regulations will operate under the Radiation Act 2005, which incorporates substantial sanctions for non-compliance. Specifically, solaria face the potential loss of their licences to operate radiation equipment in cases of substantial or repeated breaches. As this would effectively close their businesses, consciousness of these potential sanctions can be expected to encourage a high level of compliance. It can also be noted that the level of compliance with the Australian Standard in recent years was relatively high, at least in respect of certain provisions, despite its voluntary status. This can be taken as suggesting that the industry would be likely to exhibit significantly higher rates of compliance with compulsory regulatory requirements.

Reduction in skin cancers

The actual impact on solarium-related skin cancer would necessarily be significantly greater than the actual reduction in the number of solarium visits. This is because the largest part of the reduction in overall use derives from the exclusion of two particularly vulnerable groups: those with Type 1 skin and the very young. As noted in Section 1, above, those with Type 1 skin have been found to have a 110% increase in melanoma risk due to solarium use. Similarly, those first using solaria in adolescence experience a 52% increase in melanoma risk. By comparison the increase in melanoma risk due to solarium use for the general population was found to be 22% (or 36% when adjusted for other exposure factors).

The importance of this factor is difficult to model accurately. Consequently, two scenarios are modelled. In the low impact scenario, the rate of reduction in solarium-caused skin cancer is estimated at 60% and in the high impact scenario it is estimated at 80%. The former scenario effectively assumes that those who are excluded from solarium use (or otherwise choose not to use solaria as an outcome of aspects of the regulations) have on average a 20% higher risk of melanoma than the general population, while the latter scenario assumes that this group has a 60% higher average risk. Given the above data on specific comparative risk for the two main excluded groups, these scenarios are considered to both be well within the reasonable range of expected outcomes.

As noted above, the base case against which these potential reductions is measured is the current situation of around 1.5 deaths per annum due to melanoma and 12.75 new cases of melanoma per annum due to sunbed exposures in Victoria.

Based on these two scenarios, the following table estimates the expected reductions in skin cancers due to the regulations over a 10 year period.

Table 2: Estimated skin cancer reductions due to proposed regulations

| | Low scenario | | High scenario | |
|-------------------------|------------------|----------------|------------------|----------------|
| | Annual reduction | 10 year impact | Annual reduction | 10 year impact |
| Melanoma mortalities | 0.9 | 9 | 1.2 | 12 |
| Melanoma cases | 7.65 | 76.5 | 10.2 | 102 |
| SCC cases ²⁴ | 79.6 | 796 | 106 | 1060 |

Table 2 shows that between nine and 12 deaths from melanoma would be expected to be averted over the life of the proposed regulations. Between 76 and 102 cases of melanoma would also be averted, while between 796 and 1060 cases of SCC would be averted.

Data summarised by Gordon indicated that the average latency period for melanoma is, most likely, only about two years. On the other hand, the average latency period for SCC is approximately 10 years. Thus, if the regulations are assumed to have a 10-year lifespan, the benefits in terms of reductions in melanoma cases and mortalities can be modelled as occurring between year three and year 13 after the introduction of the regulations, while the reduction in cases of SCC are appropriately modelled as occurring between years 11 and years 20.

Valuation of the benefits

Two basic approaches to benefit valuation had been adopted. First, in respect of melanoma mortalities averted, a Value of a Statistical Life (VSL) figure based on revealed willingness to pay has been adopted. In fact, two scenarios have been modelled, based on two different VSL figures. The first is a figure of \$3.5 million, while the second is a figure of \$6.0 million. Both of these figures have been derived on the basis of meta-analyses of the academic research on this issue conducted in Australia recently²⁵.

Secondly, the approach taken to valuing reductions in non-fatal cases of melanoma and cases of SCC replicates that of Gordon. Gordon's model estimated only the benefits of cost savings to Medicare due to reductions in requirements for medical treatment of these conditions. The average cost of

²⁴ Gordon's model estimates that enforcement of the regulations would prevent slightly more than 10 times as many SCCs as new cases of melanoma.

²⁵ See Access Economics (2008) *The Health of Nations: The Value of a Statistical Life*. Report prepared for the Office of the Australian Safety and Compensation Council. Abelson, P. (2007). *Establishing a Monetary Value for Lives Saved: Issues and Controversies*. Paper prepared for the Office of Best Practice Regulation.

treating a non-fatal case of melanoma was estimated at \$1,272, while the average cost of treating a case of SCC was estimated at \$995.

This approach has the effect of adding a second significant source of conservative bias to benefit estimation. Conceptually, benefit estimation should include benefits attributable to reductions in productivity losses as well as benefits attributable to reductions in pain and suffering. However, quantification of both of these benefits in monetary terms is problematic and, indeed controversial.

Table 3 summarises the expected dollar values of the benefits attributable to the proposed regulations, based on the above data and methodology. All figures are expressed in present value terms.

Table 3: Estimated benefits of the proposed regulations

| | High impact scenario | | Low impact scenario | |
|---------------------------------|----------------------|---------------------|---------------------|---------------------|
| | High VSL | Low VSL | High VSL | Low VSL |
| Value of lives saved | \$55,898,208 | \$32,607,288 | \$41,923,656 | \$24,455,466 |
| Medical cost savings (melanoma) | \$100,729 | \$100,729 | \$75,546 | \$75,546 |
| Medical cost savings (SCC) | \$622,299 | \$622,299 | \$466,724 | \$466,724 |
| Total benefits | \$56,621,236 | \$33,330,316 | \$42,465,926 | \$24,997,736 |

Note: High VSL figure is \$6.0 million, low VSL figure is \$3.5 million. High impact scenario assumes 1.2 deaths per annum due to melanoma are averted. Low impact scenario assumes 0.9 deaths per annum averted.

Table 3 shows that the present value of the estimated benefits of the proposed regulations varies from a minimum of approximately \$25.0 million dollars over 10 years to a maximum of \$56.6 million. The overwhelming majority of these benefits derive from the fact that 9 – 12 lives are expected to be saved. By contrast, the reduction in medical expenses is estimated to be in the range \$532,000 - \$723,000 approximately.

An additional sensitivity analysis has also been undertaken based on the assumption of a longer, 10 year latency period between radiation exposure and melanoma diagnosis and a similar 10 year latency period between radiation exposure and death from melanoma. This reflects the fact that there is some uncertainty regarding the existence and length of a latency period for melanoma and that, while a number of papers have suggested a two year latency period, at least one paper has suggested that a 10 year latency period may be more realistic.

Under this sensitivity analysis, the benefits due to reduced incidence of, and mortality from, melanoma now occur between years 11 and 20 of the analysis, rather than years 3 – 12. Thus, the value of the benefits is more heavily discounted. Table 4, below, summarises the results of this sensitivity analysis.

Table 4: Estimated benefits of the proposed regulations – long latency

| | High impact scenario | | Low impact scenario | |
|---------------------------------|----------------------|---------------------|---------------------|---------------------|
| | High VSL | Low VSL | High VSL | Low VSL |
| Value of lives saved | \$45,473,229 | \$26,526,050 | \$34,104,921 | \$19,894,537 |
| Medical cost savings (melanoma) | \$81,943 | \$81,943 | \$61,457 | \$61,457 |
| Medical cost savings (SCC) | \$622,299 | \$622,299 | \$466,724 | \$466,724 |
| Total benefits | \$47,177,471 | \$27,230,292 | \$34,633,102 | \$20,422,718 |

Table 4 shows that, under the long latency scenario, expected benefits lie in the range \$20.4 million to \$47.2 million, compared with \$25.0 million to \$56.6 million in the short latency scenario. This represents a reduction of between 16.6% and 18.4% and indicates that the results are relatively insensitive to the assumptions made as to the latency periods for melanoma, within the plausible range.

5. Expected costs of the proposed regulations

Direct licensing costs

As noted above, a total of 272 businesses are currently licensed as solarium, with a total of 828 tanning units being operated. Current licence costs are made up of a “one-off” application processing fee (\$99.20) plus a fee based on how many units are to be possessed (\$110.20 per unit for a one year licence). Existing solarium have already paid the one-off application fee under the current interim regulations. Consequently, the expected annual revenue from licence fees is:

$$828 \times \$110.20 = \$91,245$$

Fees applicable in respect of management licences under the Radiation Act 2005 were established under the Radiation Regulations 2007 and are based on full recovery of the costs to the Department of Human Services of administering the radiation legislation. Solarium have been allocated to the lowest fee category within these regulations, as it was determined that they would be among the least costly categories of radiation sources to regulate²⁶.

As noted above, these fees have been based on cost recovery principles. Thus, the expected cost to DHS of administering the regulation of solarium is approximately equal to \$91,000 per annum. This is equal to \$758,849 in present value terms over 10 years.

For solarium businesses, the direct licensing costs involved include both the payment of these licensing fees and the time costs involved in preparing licensing applications and lodging these with the DHS.

Applications for management licences must contain:

- Details about the proposed radiation practice.
- Details about any radiation sources to be possessed
- Details about the sites where the radiation practice is proposed to be conducted.
- Details of any radiation safety systems proposed to be used e.g. shielding of radiation sources.

²⁶ This, and the fact that no periodic testing regime is established for solarium (as is required for many other radiation sources) reflects the fact that there is little danger of solarium emitting higher doses of radiation than standard as a result of malfunction. Thus, there is no elevated risk to users as a result of machine malfunction.

The amount of detail required to be provided in relation to the above issues under the Radiation Act depends on the complexity and nature of the practice. In the case of solarium businesses, the amount of detail required is quite low. Thus, the costs of preparing and lodging licence applications are also expected to be low. Applications can be transmitted either in paper or electronic form.

Given the limited nature of the information required and the ability to lodge licence applications electronically, it is estimated that the time cost to business to undertake these tasks be approximately equal to the time taken by DHS to assess licence applications. Given that the latter has been estimated above to cost approximately \$91,000 per annum, this implies that the value of the time taken by business to compile and submit licence applications will also be of the order of \$91,000 per annum.

Thus the total licensing costs to be borne by business are estimated at approximately \$182,000 per annum. This is equal to \$1.5 million in present value terms over 10 years.

Other costs to solarium businesses

In addition to the cash costs of licensing, discussed above, solarium operators will incur costs associated with the need to undertake skin type assessments, obtain written consent from clients and verify that younger users are 18 years of age or over. These costs are likely to be quite small in size.

The largest individual cost is likely to be that of conducting skin type assessments. No specific method for conducting skin type tests is required to be used. However, a widely adopted approach is to adopt the Fitzpatrick Skin Typing Test²⁷. This test contains 10 questions, measuring genetic predisposition, reaction to sun exposure and tanning habits. It is likely that about 5 - 10 minutes would be required to complete this test, with the solarium operator being required to calculate the results and, presumably, to check their plausibility against visible evidence. However, each client would need to complete the test only once at each solarium. Thus, this is a “one-off” cost for the solarium proprietor.

The costs of obtaining written consent and of verifying ages are also “one-off” costs in respect of each client, rather than being ongoing costs borne at each visit. The time taken to complete these requirements is expected to be minimal.

²⁷ For an example of this test, see: http://www.spa-medical.com/fitzpatrick_skin_typing_test.htm

It must also be noted that these requirements are contained within the current Australian Standard. Thus, additional costs will be incurred only by those solarium operators who do not currently comply with the standard.

As an indicative calculation, it is assumed that the time taken to administer the skin type test and obtain written consent will average 10 minutes per client. In the first year of operation of the regulations, the test will need to be administered to all clients who have not had it administered as a result of voluntary adherence to the Australian Standard by their solarium. As noted above, compliance with this provision was 50% in 2006. Thus, the number of tests to be carried out in year 1 will be equal to 50% of the total number of solarium clients. In subsequent years, new solarium clients and those who change solaria will need to complete the test and sign a consent form. This group is assumed to account for 10% of solarium users.

As noted in Section 1, the proportion of the Victorian population using solaria has previously been estimated, based on survey data, at 3%. However, the recently observed 30% decline in the number of solaria can be expected to have resulted from a decline in patronage that would be likely to be at least equal in extent. Thus, the number of clients that will complete the tests in year 1 is estimated as being equal to 2.1% of the population, less the 50% of this group that has already completed the test due to solaria voluntarily complying with the Australian Standard. Thus, slightly more than 1% of the population will be affected, equal to around 50,000 clients. In subsequent years, 0.2% of the population will be affected, or 10,000 clients per year.

Based on average weekly earnings and a 75% labour on-cost figure, the cost per test/consent form is $\frac{1}{6}$ hour \times \$29.25 \times 1.75 = \$8.53 per test. Thus, the cost of testing and consent forms in year 1 will be $\$8.53 \times 50,000 = \$426,500$. The cost in each subsequent year will be equal to one fifth of this amount, or \$85,300. The present value of these costs over 10 years is equal to \$1.0 million.

Reduced revenues for solarium industry

The adoption of the regulations is expected to reduce substantially the current extent of solarium tanning. As noted above, the incidence of tanning in the general population is expected to fall by around 50% following implementation.

No data on the current turnover in the industry are available. It should be noted that many sunbeds are operated as a part of another business (e.g. hairdresser or beautician), rather than being a part of a dedicated solarium business. This adds to the difficulty of estimating revenue effects.

One recent business for sale advertisement claims revenue of \$67,600 for a four bed solarium business. This is equal to approximately \$16,900 per sunbed.

Such a figure can obviously be taken as indicative only. However, given that there are currently 828 registered sunbeds, adopting this figure as an average annual revenue per sunbed would suggest that annual revenue for the solarium industry could be of the order of:

$$828 \times \$16,900 = \$13,993,200$$

This would imply that, if solarium use were to be reduced by 50%, as predicted in the previous section, the regulations could lead to a reduction in revenue of around \$7.0 million per annum. This is equivalent to a reduction in revenue of \$58.2 million in present value terms over the expected 10 year life of the regulations.

This is not an economic cost. In economic terms, the majority of this amount can be considered to be a transfer from the solarium industry to producers of a range of other goods and services. That is, to the extent that demand for solarium services declines, this can be expected to result in consumers switching expenditure to other services.

Some of these services would be expected to be provided by the same service providers: for example, many former solarium users (including those who may continue to use a solarium but do so less frequently due to increased risk awareness) may choose to use spray tanning as an alternative. This service is often offered by solarium businesses. To the extent that this shift in demand occurs, it would not represent a loss of revenue to solarium businesses but, rather, a simple shift from sales of one product to another.

Loss of utility due to reduced individual choice

While the loss of revenue for solarium operators has been identified above as constituting a transfer, rather than a real economic cost, economic theory does indicate that a relatively smaller economic cost will often be associated with changes in expenditure patterns that are induced by regulation.

If a consumer is assumed to be fully informed then, in the absence of externalities or other market failures, their expenditure choices are assumed to be utility maximising. Thus, if a regulation causes changes in those choices, it is regarded as having a distorting effect on consumer preference and, as a consequence, leading to a reduction in total consumer utility. The size of this reduction in total consumer utility is normally equal to only a small proportion of the total quantum of expenditure that is transferred to other consumption possibilities. Thus, in the current case, the potential loss of consumer utility would be equal to some small proportion of the estimated total reduction in expenditure on solarium services of \$58.2 million over 10 years.

In the case of the proposed regulations, it is most likely that the loss of consumer utility involved will be very small. The net impact on consumer utility can be regarded as being the sum of three separate effects:

- First, some consumers who are fully informed of the risks involved, who currently choose to use solarium services regardless of those risks and who would be excluded from using solaria by the regulations will suffer a loss of utility. The only identifiable group in this category is those with type 1 skin;
- second, some currently ill informed consumers who currently use solarium services will, as a result of the aspect of the regulations aimed at improving consumer information and reducing the prevalence of potentially misleading information, choose to no longer use solarium services, or to use fewer solarium services. The reduction in consumption by this group will be associated with an increase in consumer utility, since choices will increasingly be made on the basis of full information; and
- third, some consumers who are deemed to be unable to give informed consent will be excluded from using solarium services. This group comprises those under 18 years of age. The impact on consumer utility of excluding this group from solaria cannot be objectively determined²⁸.

There is necessarily a considerable degree of uncertainty as to the relative size of these three impacts. However, the fact that they operate in different directions and that they therefore offset each other, at least to some extent, and suggests that any net loss in consumer welfare as a result of the introduction of the proposed regulations will be very small.

Summary of costs

Given the above it is clear that, from the viewpoint of society as a whole, the only costs associated with the proposed regulations are those directly related to the licensing scheme and the enforcement of the regulations. These have been estimated at \$2.5 million over ten years in present value terms.

²⁸ Gordon's model assumes that some proportion of this group will commence using solarium services as soon as possible after reaching 18 years of age. For this group, the prohibition on the use of solaria when under 18 is, presumably, associated with a loss of utility. However, for those who, at 18 years of age, decide not to engage in solarium use the prohibition on them using solaria when under 18 would, at least arguably, increase utility.

6. Identification and assessment of feasible alternatives

Two feasible alternatives to the proposed regulations have been considered in the course of the development of the proposed regulations. The first would involve implementing fully the licensing requirements of the Radiation Act 2005, embracing both management and use licences, rather than providing for conditional exemptions from the need for use licenses, as currently proposed. The second is similar to the proposed regulations, but differs in that the use of solaria by persons under 18 years of age would not be prohibited. Rather, persons aged under 18 years would be able to use solaria provided that they supplied a written statement of permission from their parent and/or guardian. This is effectively the position under the current, interim regulations.

A third alternative, involving reliance on education campaigns targeted at young people in preference to a regulatory approach has also been discussed. However, initial analysis has indicated that it fails on the criterion of feasibility – i.e. of being reasonably capable of achieving the identified regulatory alternative. Consequently, the benefits and costs of this alternative are discussed in lesser detail.

6.1. Regulating to require both management and use licences

6.1.1. Expected benefits of the alternative

In general terms, the benefits of this alternative would be that it would provide for a higher level of control over the actions of solarium employees. This would mean that there was a greater possibility of holding solarium staff accountable for ensuring that the requirements of the regulations were enforced in practice. Specifically, the sanction of being able to cancel the use license of a particular staff member in cases of significant and/or repeated breaches of the regulatory requirements would be available. The practical impact of cancelling a use license would be to prevent a staff member working in any capacity that was related to the use of solaria.

This approach would be expected to increase, at least to some degree, the observed level of compliance with the requirements to be implemented by the proposed regulations.

6.1.2. Expected costs of the alternative

Limited information is available as to the number of employees in the solarium industry. However, it is apparent that this alternative would involve a very substantially larger licensing task than that which is implied by the proposed regulations.

As an indicative example, if it is assumed that there is an average of five employees per solarium business premises, this alternative would involve the processing of 1,812 licenses²⁹, rather than fewer than 272 licences under the proposed regulations. If the average cost involved with use licenses were the same as that involved with management licences, this would imply a total licensing related costs of \$900,000 per annum, or \$7.5 million over 10 years in present value terms³⁰. This represents a cost increase of \$750,000 per annum, or \$6.25 million in present value terms over the anticipated 10 year life of the regulations.

6.1.3. Break even analysis

As noted above, the expected costs of this alternative have been estimated to be roughly \$6.25 million higher over 10 years than under the proposed regulations. By contrast, the expected benefits of the proposed regulations have been estimated as lying within the range \$25.0 million to \$56.6 million over 10 years.

The alternative will have a higher net benefit than the proposed regulations only if the benefits associated with it are at least \$6.25 million greater than the proposed regulations. The alternative would need to be between 11% and 25% more effective than the proposed regulations in order for this condition to be met.

Moreover, even in this case, the alternative would still have a substantially smaller benefit/cost ratio than the proposed regulations.

6.2. *Requiring parental permission for under-18 year olds*

6.2.1. Expected benefits of the proposed alternative

The major benefit of this alternative is that it preserves a greater degree of individual choice as to the use of a solarium than do the proposed regulations. Under this alternative, parents who felt that their 16 or 17 year old children were capable of making an informed choice, and who did not wish to prevent them

²⁹ i.e. 5 use licences/premises x 308 premises + 272 management licences.

³⁰ That said, it is arguably likely that the costs involved with user licensing would in practice be somewhat smaller than those estimated above in relation to management licences.

from using solaria, would be able to give them permission to do so. These adolescents would then not be prevented from using solaria.

It can be noted that this alternative is consistent with the approach taken under the current Australian Standard on solarium use, and under the current interim regulations, whereas the proposed regulations go further in this area. More broadly, it is common for regulation to recognise parental responsibility for their children in a wide range of relatively low-risk circumstances by allowing them to make a decision as to whether their child may participate in a risky activity. This alternative would be consistent with that general regulatory approach.

On the other hand, this alternative would be expected to be substantially less effective than the proposed regulations in reducing solarium use. As Gordon points out, the 16 to 24 age group is the largest demographic for solarium use. Consequently, the result of continuing to allow 16 and 17 year olds to use solaria is likely to be that there will be significantly higher solarium use than under the proposed regulations.

Moreover, research demonstrates that first use of solaria at a young age very substantially increases the risk of acquiring a skin cancer. Thus, the effectiveness of this alternative in achieving the underlying objective of reducing the incidence of skin cancer due to solarium exposure would be very much compromised.

6.2.2. Expected costs of the alternative

The direct licensing costs of this alternative would be identical to those of the proposed regulations.

6.3. *Education programs aimed at young people*

A third potential alternative is to address concerns regarding solarium use via education programs aimed primarily at young people. The current context is one in which some public education campaigns (e.g. the Cancer Council's "Fashion to Die For" campaign) are already in place. However, in the absence of a regulatory response, it is assumed that a more substantial public education campaign would be required, involving addressing the issue in Victorian secondary schools and providing additional funding for a general media campaign aimed specifically at young people.

6.3.1. Expected benefits of the alternative

Short-term responses to the substantial media coverage of the Clare Oliver story and the subsequent “Fashion to Die For” campaign appear to have been substantial, given the apparent decline in solarium numbers in Victoria of around 30% over the past year. An ongoing campaign aimed particularly at young people would potentially maintain this short-run behavioural effect, at least to a substantial degree, in the medium term.

However, this alternative would be expected to have substantially smaller benefits than the proposed regulations, for several reasons. First, this alternative relies entirely on behavioural change. It has been noted in a range of public policy contexts (e.g. smoking) that adolescents demonstrate relatively low susceptibility to health messages pointing out the dangers of particular behaviours.

Second, regardless of the posited extent of behavioural change among the under-18 age group, the size of the impact on their solarium use can only be smaller – and probably significantly smaller – than would be the case under the proposed total prohibition. Given the evidence cited above that this is a relatively large user group, this suggests that the benefits of this option would be significantly lower than under the proposed regulations.

Third, a campaign aimed primarily at young people would be likely to have only a relatively small impact on other high-risk user groups. In particular, it can be expected to have a substantially smaller impact on solarium use by people with Type 1 skin than would the proposed total prohibition. Again, this group represents around 19% of all solarium users, suggesting that lower effectiveness in this regard would also mean that the benefits of this alternative are substantially reduced relative to the proposed regulations.

Fourth, this option does not include provisions that would regulate the behaviour of the solarium industry in areas such as exercising control over exposure times and ensuring that maintenance of sunbeds is not carried out in a way that would increase their emissions.

6.3.2. Expected costs of the alternative

This alternative could be expected to have costs that are somewhat lower than those of the proposed regulations, since it would not involve either licensing or enforcement-related activities. On the other hand, the cost of providing an effective education program to all upper secondary students would not be insubstantial. Indicative costings would include the following:

- There were 370 secondary schools and 204 combined primary/secondary schools in Victoria in 2007 (ABS 4221.0). Thus, programs would need to be delivered in 574 schools approximately³¹.
- If a single, two hour session were offered at each year level, with years 9,10,11 and 12 covered, this would imply a total of 2,256 education sessions being conducted over 4,512 hours.
- If each session is presented by two presenters (given the implicit large session sizes, this may be necessary for practical reasons), each earning average weekly earnings, the total wage cost would be [9,024 x \$29.25 = \$263,952 ³²]
- Addition of 75% on-costs would raise the total labour cost to \$461,916.
- It is assumed that written materials are made available to all students. There were 380,342 full-time secondary students in Victoria in 2007. If approximately 60 per cent of this total is assumed to be in years 9-12, this implies a total of 228,205 students receiving written materials. At a notional cost of \$10 per student for printing and distribution, this is equal to \$2,282,050 in costs for distribution of supporting literature.

The above suggests a total cost of \$2,282,050 + \$461,916 = \$2,744,832. If it is assumed that the education programs are repeated annually for all students in order to ensure maximum effectiveness by periodically reinforcing the message and progressively increasing the detail and sophistication provided as students progress through older year levels, this cost would become an annual one.

The present value of these costs over ten years would be \$22.8 million. It should be noted that these costs relate only to the provision of an education program in the schools context. Were a media based program to be adopted in conjunction with the schools program, significant additional costs would also be incurred.

³¹ This will be an over-estimate, to the extent that some of the combined schools do not include students in years 9-12. However, this group is believed to be a small number.

³² Full-time Adult ordinary time earnings in February 2008 = \$1123.30/week, divided by average hours of 38.4 = \$29.25/hour. (ABS 6302.0, ABS 6306.0).

7. Conclusion

The proposed regulations are expected substantially to reduce the use of solaria in Victoria, particularly by those groups most at risk of contracting skin cancer due to exposure to ultraviolet radiation. It will do this by prohibiting access to solaria by certain vulnerable groups, by improving understanding of the risks associated with solarium use and by preventing certain types of potentially misleading advertising.

It is estimated that the implementation of the proposed regulations will reduce the number of deaths due to melanomas caused by sunbed exposure by between nine and 12 over the 10 year life of the regulations. In addition, between 76 and 102 new, non-fatal cases of melanoma are likely to be avoided over the 10 year life of the regulations, while between 796 and 1,060 cases of SCC are also expected to be averted over the same period.

In dollar terms, these benefits have been valued at between \$25.0 million and \$56.6 million in present value terms over 10 years. It should be noted that the benefits estimated in respect of both non-fatal melanoma and SCC relate only to reductions in the costs of medical treatment. That is, no valuation of the reduction in pain and suffering consequent on the lowering of the incidence of these kinds of skin cancers has been factored into these benefit calculations. Clearly, however, this constitutes an extremely important intangible benefit which should also be taken into account. Reduced productivity losses should also ideally be taken into account.

The expected economic costs of the regulations are quite small by comparison with these benefits. Direct licensing costs to solarium businesses are estimated to total only \$182,000 per annum, or \$1.5 million in present value terms over 10 years. It is clear that the solarium industry will suffer a substantial decline in turnover as a result of the implementation of the regulations. It has been estimated that this reduction in revenue may be as great as \$7.0 million per annum, or \$58.2 million in present value terms over 10 years. This is equal to 50% of the current turnover of the industry in Victoria. In practice, however, the observed decline in revenue is likely to be significantly lower than this, reflecting the fact that many consumers may choose to substitute spray tans or other products supplied by the solarium industry.

It is emphasised that this reduction in revenue constitutes a transfer, rather than an economic cost, since consumer expenditure will inevitably be diverted to other ends.

Two feasible alternatives to the proposed regulations have been considered. The first differs from the proposed regulations in requiring user licensing, rather

than providing conditional exemptions. This alternative could increase the estimated cost of licensing five fold, to \$900,000 per annum, or \$7.5 million in present value terms over 10 years. As a result, this alternative would have a lower Net Present Value than the proposed regulations unless it proved to be substantially more effective than the proposed regulations. Given that several different scenarios have been modelled in terms of the proposed regulations, the required increase in effectiveness needed for this alternative to have a higher NPV varies in the range between 11% and 25%, according to the scenario considered.

It is considered quite unlikely that effectiveness gains of this order would be achieved under this alternative. This conclusion is essentially based on the fact that the licensing of solarium business operators via the management licence system is common to the two options and that this is considered to be by far the most effective means of improving practice in the solarium industry. Management licence holders have substantial incentives, based on preserving the value of their business, to ensure good practice. By contrast, the solarium employees who would be licensed under this alternative would not face substantially different incentives under the two options, since their employers are considered to be the predominant influence in ensuring good practice.

Moreover, it is also apparent that the benefit/cost ratio associated with this alternative would be substantially inferior to that of the proposed regulations given the much higher licensing costs involved. This reflects the substantially greater costs to solarium businesses under the alternative. Finally, an additional disadvantage of this alternative is that it risks creating uncertainty as to the primary focus of responsibility for ensuring compliance with the regulations by licensing two parties, rather than simply licensing business owners. For all of the above reasons, the proposed regulations are preferred to this alternative.

The second alternative considered differs from the proposed regulations in that it would not exclude 16 and 17-year-olds from using solariums. Rather, these minors would be required to supply written permission from their parents or guardians. The major benefit of this alternative is that it allows parents to make choices on behalf of their children. Against this, the effectiveness of this alternative in preventing skin cancer would be substantially lower than that of the proposed regulations. This reflects the fact that the 16 to 24 age group is the one most likely to use solariums. Moreover, it is not widely understood that the use of solariums at a very young age very substantially increases the risk of skin cancer.

The second alternative is also inconsistent with both the consultation draft of the revised Australian Standard and the draft amendment No. 5 to the National Directory on Radiation Protection, both of which were recently released for public consultation. Should the NDRP amendment be approved, Victoria will be obliged to implement its provisions under the terms of the relevant national uniformity agreement. Hence, this alternative is unlikely to be feasible.

It has not proven possible to estimate the net present value of this alternative given a lack of data on the proportion of solarium use accounted for by 16 and 17-year-olds and uncertainty as to the precise extent of the excess skin cancer risk faced by this group. However, it can confidently be stated that the NPV of this alternative is substantially lower than that of the proposed regulations. Evidence for this proposition can be seen in graph 2, which provides Gordon's estimates of the impact on lifetime solarium use of excluding 16 and 17-year-olds. This graph clearly indicates that excluding 16 and 17-year-olds from solarium use would be expected substantially to increase the effectiveness of the regulations.

It also be noted that the revised version of the Australian standard in respect of solarium use, which has recently been released in draft form for public consultation purposes, include a prohibition on the use of solaria by those under 18 years of age. It is expected that this revised standard will be published in approximately December 2008.

Given these factors, the proposed regulations are also preferred to alternative 2.

A third alternative was also subjected to a preliminary analysis. This involves focusing on changing user behaviours through school and media based education programs aimed at young people, in preference to continuing with a regulatory approach. However, this alternative was found to be likely to be very costly, with indicative costs of \$2.8 million per year or \$22.8 million in present value terms over 10 years being assessed. Moreover, given that this alternative would rely solely on behavioural effects, it is expected to provide substantially smaller benefits in terms of reductions in skin cancer incidence and mortality than the proposed regulations. If the benefits of this option were estimated as likely to be half of those of the proposed regulations – itself a relatively optimistic scenario – the present value of the benefits would lie between \$12.5 million and \$28.8 million. This indicates that this alternative is quite unlikely to yield a positive NPV outcome. Moreover, it would clearly yield substantially lower net benefits than the proposed regulations.

Finally, it should be noted that the adoption of this option is infeasible insofar as Victoria is committed to the adoption of a nationally uniform approach to the regulation of solaria within the context of broader radiation safety legislation.

As required by the Victorian Guide to Regulation, the results of the above comparative analysis have been summarised and presented in the form of a Multi-Criteria Analysis. Four decision criteria have been identified: minimising regulatory costs, maximising regulatory benefits, consistency with national agreements and protection of the vulnerable. Each alternative (including the proposed regulations) has been scored against these four criteria, with scores

between zero and 5 being allocated. A score of 5 represents maximum performance against the criterion, so that the alternative with the highest score is preferred. Table 5, below, summarises the results of this analysis.

Table 5: Multi-Criteria Analysis of proposed regulations and alternatives

| Criterion | Proposed Regs | 2 tier licensing | No ban on < 18s | Education programs |
|--------------------------------------|----------------------|-------------------------|---------------------------|---------------------------|
| Minimising regulatory cost | -2 | -5 | -3 | -2 |
| Maximising regulatory benefits | 4 | 5 | 2 | 1 |
| Consistency with national agreements | 5 | 5 | 3 | 0 |
| Protection of vulnerable groups | 5 | 5 | 3 | 1 |
| Total score | 12 | 10 | 5 | 0 |

The following explains the scoring of the alternatives against each criterion.

Minimising regulatory cost

All options score negatively on this criterion, since each entails regulatory costs that are not incurred under the base case option of continuing with voluntary adoption of the Australian Standard. The proposed regulations and the alternative of adopting the proposed regulations without the ban on under 18 year olds using solaria have essentially the same regulatory costs, but for the additional administrative costs incurred under the latter option due to the continued need to request parental permission forms and maintain these records. Due to this additional administrative cost, the latter option is ranked slightly lower than the proposed regulations. The option of an education program has highly uncertain costs, depending on the scope and intensity of the program decided upon. However, given that the indicative analysis presented above suggested similar costs to those incurred under the proposed regulations, this option has been scored the same as under the proposed regulations. Finally, the option of two-tiered licensing obtains a very low score because it has been estimated to entail costs that are approximately five times higher than under the proposed regulations.

Maximising regulatory benefits

The option of two tiered licensing obtains the highest score against this criterion, since it is assumed to be more effective, at least at the margin, in ensuring compliance with the substantive requirements to be imposed. However, the proposed regulations score only slightly lower, since they are expected to yield broadly similar benefits. The option of regulating without banning under 18 year olds scores substantially lower, since this group is believed to be a major user group, as well as being a high risk group and this option would be substantially less successful in protecting this group from solarium-related harms. Finally, the alternative of education programs is expected to entail the lowest benefits, since it would be less than fully effective in barring access by either of the two main vulnerable groups – i.e. those with type 1 skin and those under 18 years of age.

Consistency with national agreements

Both the proposed regulations and the “two tiered licensing” option are consistent with Victoria’s national obligations and so score the maximum, while the remaining two options are inconsistent with these obligations. The option of regulating but failing to ban access by under 18 year olds is partially consistent with the national obligations and so scores three points, while the education campaign option scores the minimum (zero points) as it is not at all consistent with these obligations.

Protection of vulnerable groups

Both the proposed regulations and the two tiered licensing option are expected to be effective in preventing access by the identified vulnerable groups and so score five points. The option of not banning under-18 year olds but implementing the remainder of the proposed regulations is partially effective in this regard and scores three points. The option of an education campaign is considered to be relatively ineffective, particularly due to the likely lack of impact on under-18 year olds, and scores one point.

Conclusion

As Table 5 demonstrates, the proposed regulations score highest, with 12 points. The two tier licence option scores next most highly with 10 points, while the option of regulating without banning under-18 year olds scores 5 points. The option of relying on an education campaign scores lowest with 0 points.

Consequently, it is proposed to proceed with the regulations.

8. Interstate and international comparisons

8.1. Interstate comparisons

The proposed regulations are consistent with national standards in relation to solarium regulation that have been developed under the auspices of ARPANSA³³. These national standards are yet to be formally endorsed by the Health Minister's Council. However, this endorsement is expected to occur later in 2008.

Despite the fact that the national standards have yet to be formally endorsed, South Australia has already adopted regulations that are consistent with them, while Western Australia is understood to be in the process of developing similar regulations at present. This early action reflects a view that urgent action is required in this area.

Once the national standards are agreed by the Health Minister's Council, nationally consistent regulation will be brought into effect in all Australian States and Territories.

Prior to the development of the national standards, the approach taken to minimising risks has been to promote compliance with the Australian Standard in relation to solarium use (*Australian Standard AS/NZS 2635:2002 Solaria for Cosmetic Purposes*). Thus, until recently, no State or Territory has formally regulated the use of solaria.

8.2. International comparisons

The World Health Organisation recommended in 2003 that governments should consider introducing regulation governing the use of sunbeds³⁴. Regulation of the solarium industry is, in fact, now widespread internationally and is apparently expanding. According to Makin *et al* (2007)³⁵:

Legislation is already in place in 28 States of the United States and several European countries, including France, Belgium and Sweden. Several more States and countries are considering introducing similar legislation.

³³ The Australian Radiation Protection And Nuclear Safety Agency

³⁴ Sinclair C. *WHO Guidance Brochure: Artificial Tanning Sunbeds*. Geneva (CHE): World Health Organization; 2003. p. 7.

³⁵ Makin, J., K. Dobbinson, S., J. and Herd, N., L. (2007), "The increase in solariums in Australia, 1992-2006", *Australian and New Zealand Journal of Public Health*, vol. 31, no. 2, p. 191-192.

A number of different regulatory frameworks currently govern solarium use in Europe. However, France, Norway, Sweden, Austria, Finland, Spain, Belgium and Portugal all have some form of solarium regulation in place. In addition, the United Kingdom³⁶ and Germany currently have voluntary regulation. The following summarises the take-up of key features of solarium regulation in Europe³⁷:

Irradiance.

All European Union countries which regulate solariums have recently implemented a uniform limit of 0.3 W/m² for the total irradiance of solarium units.

Registration

Solariums require registration with the statutory authority in France, Norway and Sweden.

Access by minors

All countries except Belgium ban under 18 year olds from using solariums. Belgium bans only under 15 year olds.

Skin type 1

The exclusion of skin type I persons is required in France, Sweden, Austria, Finland and Spain. Austria also bans persons with skin type II. Norway, Belgium and Portugal do not restrict skin types.

Interval between exposures

The 48hr minimum interval between exposures control is required in France, Norway, Sweden, Finland, Spain and Belgium. Portugal and Austria do not have this requirement.

Harmonisation agenda

Work is continuing in Europe towards harmonisation of solarium regulations. The European Society for Skin Cancer Prevention has recently submitted a "Code of Practice for Artificial Tanning" to the European Commission for consideration to be given to its implementation as a uniform requirement for all jurisdictions with solarium regulation. The Code covers training, the provision of

³⁶ Scotland has recently passed a Bill to implement solarium controls via legislation that will see under 18s banned and solarium supervision made a requirement.

³⁷ Source: Data supplied by the Department of Human Services.

information and advice to consumers, consent forms, recording of customer exposures, supervision of customer use, testing and certification of tanning equipment, inspections of solarium and provision of eye protection. As is apparent, the content of this European Code is broadly consistent with that of the proposed regulations and the draft National Directory.

9. Administrative burden statement

As a result of the Victorian government's 2006 *Reducing the Regulatory Burden* policy statement, all significant new administrative burdens created by legislation or regulation are required to be measured using a Standard Cost Model methodology, established by the Department of Treasury and Finance. The results of this analysis are generally expected to be reported in the RIS in respect of proposed regulations that would impose significant new administrative burdens.

Administrative burdens are defined as including all costs of gathering, storing and transmitting information to government that is required to be collected as a result of a regulatory provision. In the current context, the costs to business of the licence application process can be considered to be administrative burdens. These have been estimated above as being in the region of \$75,000 per annum³⁸. In addition, it is arguable that the costs associated with completing skin-type tests and obtaining written consent from users fall within the definition of administrative burdens. These costs have been estimated above at \$1.0 million in present value terms over 10 years, equal to an average cost of \$100,000 per annum. Thus, total administrative burdens are estimated to average around \$175,000 per annum.

This is significantly smaller than the "materiality threshold" of \$250,000 per annum for new administrative burdens that is typically adopted under the policy. Consequently, no SCM analysis has been conducted in this case.

³⁸ i.e. Excluding the actual licence fee.

10. Consultation

There has historically been general support from solarium industry associations for the Australian Standard. Consequently, early policy responses to concerns as to the observed low rate of compliance included DHS writing to solarium operators, in both 2002 and 2005, reminding them of the requirements of the Australian Standard and inviting industry members to work with the department to increase compliance with the Standard. These initiatives met with a limited response.

In May 2006, DHS held a consultation forum with solarium operators where the requirements of the Australian Standard were discussed. The majority of solarium operators and suppliers who attended that forum expressed support for the Australian Standard and its requirements. However, the forum was poorly attended by the industry and, as noted above, compliance surveys continued to show low levels of compliance with many of the elements of the Standard.

During the development of the current Interim Regulations in late 2007 a reference group was formed, comprising key industry stakeholders, government representatives, the Cancer Council and consumer groups. The reference group was convened on two occasions to discuss the regulations and their implementation. The reference group was generally supportive of the introduction of regulation and provided valuable input on specific regulatory issues as well as implementation issues.

Prior to the regulations taking effect in early 2008, two industry information sessions were held which provided an opportunity to obtain direct feedback from the industry. The feedback from this group was generally positive with many supportive views expressed regarding the adoption of uniform standards that the regulations would introduce and enforce.

On several occasions throughout the process, information packs have been mailed out to the industry to provide details and general assistance with the licensing process and requirements. This has resulted in many general enquiries received from solarium business owners with an overall sentiment of support for the introduction of controls to the industry being expressed.

In relation to the main substantive change between the interim regulations and the proposed regulations (i.e. the increase in the minimum age for a client to be exposed to UV in a tanning unit to 18 (as opposed to 16 with parental/guardian consent)), consultation has been undertaken in several contexts. First, this issue was raised at both a Reference Group and in meetings with industry prior to the commencement of the current interim regulations. At that time it was raised in the context of possible moves to change the Australian Standard reference to age

limits. It appeared that there was support for such a move and no alternative views were expressed at that time. It was noted by industry that the change would remove the need to obtain parental or guardian consent. We note that a new draft Australian Standard is currently undergoing public consultation and contains similar provision, making the minimum age of exposure to be 18.

11. Statement of compliance with National Competition Policy

The National Competition Policy Agreements (“NCPA”) set out specific requirements with regard to all new legislation adopted by jurisdictions that are party to the agreements. Clause 5(1) of the Competition Principles Agreement sets out the basic principle that must be applied to both existing legislation, under the legislative review process, and to proposed legislation:

The guiding principle is that legislation (including Acts, enactments, Ordinances or Regulations) should not restrict competition unless it can be demonstrated that:

- (a) The benefits of the restriction to the community as a whole outweigh the costs; and*
- (b) The objectives of the regulation can only be achieved by restricting competition.*

Clause 5(5) provides a specific obligation on parties to the agreement with regard to newly proposed legislation:

Each party will require proposals for new legislation that restricts competition to be accompanied by evidence that the restriction is consistent with the principle set out in sub-clause (1).³⁹

Accordingly, every regulatory impact statement must include a section providing evidence that the proposed regulatory instrument is consistent with these NCP obligations. The recently released OECD Competition Assessment Toolkit⁴⁰ provides a checklist for identifying potentially significant negative impact on competition in the RIA context. This is based on the following three questions:

- Does the proposed regulation limit the number or range of suppliers?
- Does the proposed regulation limit the ability of suppliers to complete?
- Does the proposed regulation limit to the incentives for suppliers to compete vigorously?

According to the OECD, if all three of these questions can be answered in the negative, it is unlikely that the proposed regulations will have any significant negative impact on competition.

³⁹ Clause 5, Competition Principles Agreement, 11 April 1995 accessed at www.ncc.gov.au/pdf/PIAg-001.pdf

⁴⁰ See *Integrating Competition Assessment into Regulatory Impact Analysis*. OECD, Paris, 2007. (DAF/COMP(2007)8).

In the case of the proposed regulations, all three of the above questions must be answered in the negative. The regulations impose only minimal cost increases on solarium businesses. Moreover, while the reductions in demand for solarium use that they are likely to entail may lead to a diminution in the number of solarium businesses, this is not considered to be anti-competitive in the above terms for two reasons. First, there is no "limit" on the number of suppliers being imposed as a result of the regulations. Given this, and the current large numbers of solarium businesses, it is not considered likely that the regulations will lead to any discernible reduction in competitive pressures in this industry.

Consequently, it has been concluded that the proposed regulations are fully compliant with the National Competition Policy Agreements.

12. Compliance and enforcement strategy

Solarium businesses are already registered under the Radiation Act 2005 as a result of the operation of the interim regulations. The number of businesses that have been registered has been consistent with prior expectations, based on estimates of the number of solarium businesses currently operating. Thus, compliance with the licensing requirements of the regulations is considered already to be at a high level and is expected to be maintained.

Substantive compliance with the licence conditions imposed via the regulations will be achieved via a number of strategies.

First, a program of inspections will be undertaken on all licence holders. These inspections, undertaken by the department's authorised officers, will assess the practice for compliance with the legislation. The approach to be taken will involve following a standard operating procedure to assess compliance with the conditions of licence and to instigate improvements to communication and educational efforts where needs are identified. Provided the premises are open for business, the presence of the management licence holder will not be required at an inspection. Within the first year of regulation, it is expected that all licence holders will be subject to an inspection, with a view to follow up inspections occurring over a subsequent two year period.

Where evidence of non-compliance with the legislation is obtained, a range of actions may be taken ranging from advice, warnings of the implications of a repeated breach and sealing of the tanning units. In the case of a sealed tanning unit, a follow up inspection will occur once the non-compliance has been rectified and removal of the seal will take place.

In extreme cases of repeated non-compliance, initiation of enforcement action under the Act will be undertaken. This incorporates a range of actions culminating in prosecution and suspension or cancellation of licences. The maximum penalties associated for non-compliance with licence conditions under the Act range from \$132,000 for a person to \$660,720 for a company.

Secondly, it is anticipated that in comparison to other radiation sources under the Radiation Act, there will be a greater probability of receiving consumer complaints related to tanning units. These may also include complaints of unlicensed practices or coin operated practices which do not conform to the regulations. Departmental responses to consumer complaints will include contact with the practice in question to discuss their overall compliance requirements and a site inspection based on the probability of non-compliance. Enforcement action under the Act may then be taken. In the case of suspected coin operated practices, a site inspection would take place and the tanning unit

sealed until such time that the coin operated element of the practice is removed, compliance with the associated licence conditions can be demonstrated and a licence has subsequently been approved.

13. Evaluation strategy

Section 134 of the Radiation Act 2005 requires that the Secretary of DHS publish an annual report in each financial year that:

- describes activities in relation to the Act;
- Includes a summary of all authorities issued, renewed, suspended, cancelled, varied, transferred or surrendered during that year;
- All radiation incidents investigated during that year; and
- A summary of all prosecutions for offences against the Act or the regulations.

A component of this report will address issues relating to tanning units.

In addition to complying with these statutory requirements, DHS proposes to adopt a number of further measures to monitor the performance of the regulation of tanning units in the medium term. This will involve analysis of the licensing database to monitor the results of inspections, investigation of any consumer or other complaints about tanning units and tracking the number of tanning unit relate inquiries during the year.

The results of these additional initiatives would be included in the Annual Report.

Appendix 1: Radiation Amendment (Tanning Units and Fees) Regulations 2008

STATUTORY RULES 2008

S.R. No. /2008

Radiation Act 2005

Radiation Amendment (Tanning Units and Fees) Regulations 2008

The Governor in Council makes the following Regulations:

Dated:

Responsible Minister:

DANIEL ANDREWS
Minister for Health

Clerk of the Executive Council

1 Objective

The objective of these Regulations is to –

- (a) amend the Radiation Regulations 2007 to –
 - i. prescribe a commercial tanning unit to be a non-ionising radiation apparatus; and
 - ii. prescribe management licence fees for the possession of a commercial tanning unit; and
 - iii. make provision for the waiver, reduction or refund of the application processing component of the prescribed fee for an application for a use license.
- (b) revoke the Radiation (Tanning Units Amendment) Regulations 2007.

2 Authorising provision

These Regulations are made under section 139 of the **Radiation Act 2005**.

3 Commencement

These Regulations come into operation on 30 January 2009.

4 Principal Regulations

In these Regulations, the Radiation Regulations 2007ⁱ are called the Principal Regulations.

5 New Definition Inserted

In regulation 4 of the Principal Regulations **insert** the following definitions –

“**commercial tanning unit** means a tanning unit that is not a domestic tanning unit;

domestic tanning unit means a tanning unit that is –

- (a) located at residential premises; and
- (b) is not used for fee or reward;

tanning unit means an electrically powered apparatus designed to produce tanning of the human skin by utilising ultraviolet radiation but does not include a domestic tanning unit:”.

6 New Regulation 6A inserted

After regulation 6 of the Principal Regulations **insert-**

“**6A Non-ionising radiation apparatus**

For the purpose of paragraph (b) of the definition of **non ionising radiation apparatus** in section 3(1) of the Act, a commercial tanning unit is prescribed to be a non ionising radiation apparatus.”.

7 New regulation 22 inserted

After regulation 21 of the Principal Regulations **insert** –
“**22 Secretary may reduce, waive or refund payment of application use licence fee**

The Secretary may, in relation to an application for a use licence –

- (a) reduce; or
- (b) waive; or
- (c) refund payment in whole or in part –

the application processing component of the prescribed fee referred to in regulation 11(a).”.

8 Licence fees for possession of non-ionising radiation apparatuses that are tanning units

In Schedule 6 to the Principal Regulations, after the item relating to possession of sealed sources with activity greater than 400 GBq **insert**

–

| | | | |
|---|----------------------------|----------------------------|------------------------------|
| “Possession of a non-ionising radiation apparatus that is a commercial tanning unit | 10 fee units per apparatus | 19 fee units per apparatus | 27 fee units per apparatus”. |
|---|----------------------------|----------------------------|------------------------------|

9 The Radiation (Tanning Units Amendment) Interim Regulations 2007 are revoked. ⁱⁱ

ENDNOTES

ⁱ Reg. 4: S.R. No. 89/2007 as amended by S.R. No. 148/2007.

ⁱⁱ Reg. 9: S.R. No. 148/2007

Appendix 2 Contacts for Comment

By email to:

radiation.safety@dhs.vic.gov.au

By post to:

Department of Human Services
GPO Box 4057
Melbourne 3001
Attention: Radiation Safety Section

Telephone Enquiries:

1300 767 469